RetCam Shuttle

Ophthalmic Imaging System

User Manual

PN 20-000225 Rev. A
For use with
software version 5.2

CE

Caution: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

Clarity
medical systems

Copyright

EC REP

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1 Introduction

The **RetCam Shuttle Ophthalmic Imaging System** (system) is designed to allow the quick and easy capture of wide field, high resolution, fully digital images and videos of the eye.

Indications for Use

For general ophthalmic imaging, including retinal, corneal, and external.

Warnings and Cautions

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

WARNING: Prior to using the system, read all user safety information.

WARNING: Before using this equipment to acquire images from patient eyes, users must be trained in proper clinical technique by personnel authorized by Clarity.

WARNING: The RetCam system is designed and tested as a system. Omission or substitution of RetCam components may adversely affect system performance and is strongly not recommended.

WARNING: Unauthorized modifications or additions to the RetCam system (including hardware and software, etc.) could adversely affect system function and will void the warranty.

WARNING: Carefully inspect and clean the lens piece before each use. DO NOT USE if the lens piece has nicks, breaks, scratches, or rough surfaces that may damage the eye.

WARNING: To mitigate the potential for excess light exposure, always start at the lowest light intensity level and increase if necessary. Use only the shortest amount of exposure time necessary; no greater than 5 minutes.

WARNING: Use care when contacting the eye; i.e., use the least amount of pressure and/or movement necessary.

WARNING: To avoid the risk of electric shock, the equipment must be connected to a supply mains with protective earth.

WARNING: To mitigate the potential for excess light exposure, the user should avoid looking directly at the illuminated light source.

WARNING: A risk/benefit ratio must be assessed before confirming a patient for RetCam imaging if they are photosensitive, concomitantly exposed to photosensitizing agents, or aphakic.

System Hardware

The RetCam Shuttle system consists of modules mounted in a stable, high quality integrated mobile cart for easy, safe transport from one location to another. The four casters allow for easy maneuverability and positioning. Figure 1 and Figure 2 below illustrate the system hardware.

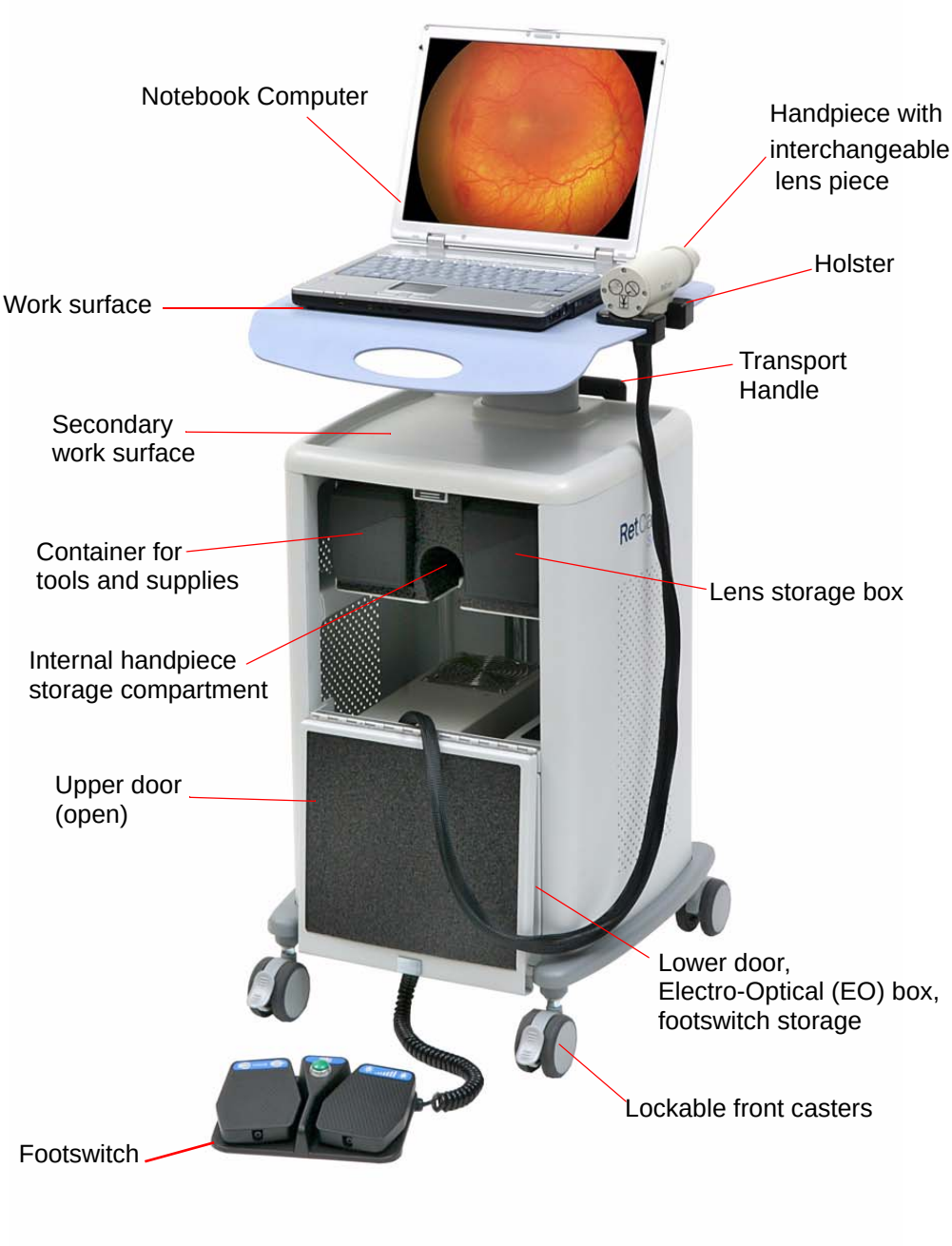


Figure 1 RetCam Shuttle Imaging System (Image representative only)

Hardware Components

- **Notebook Computer:** Pre-loaded with RetCam system software. The notebook computer includes a DVD/R/RW drive, integrated network adapter and USB ports.
- **Handpiece:** Contains the camera. Lightweight and easy to position, it has a long cable for easy reach. Use with changeable lens pieces.
- **Handpiece Interconnect Harness:** Comprises three separate cables: the lamp (fiber optic) cable for subject illumination, the camera controller cable, and the focus motor cable.

Note: Always return the handpiece to the holster when not in use. The handpiece cable can be draped over the transport handle, but do not wrap it tightly or damage to the fiber optic may result.

- **Electro-Optical (EO) Box:** Contains the camera control unit, illumination lamp, and the control circuitry. (See The Electro-Optical Box (EO Box) on page 21 for more details.)
- **Footswitch:** Provides optical means to control illumination intensity, camera focus, and SNAP.
- **Storage Compartment(s):** All units have storage compartments for lens pieces, tools, and supplies.
- **Transport Handle:** Extends to tilt and roll the cart to another location.

Figure 2 Handpiece and Lens Piece

Lens Model	Application	Common Field of View
D1300	Premature Infant	130 Degrees
B1200	Standard Baby	120 Degrees
E800	High Contrast Children's & Adults	80 Degrees
C300	High Magnification	30 Degrees
PL200	Portrait Lens	N/A

Figure 3 Shuttle with all items stowed

Storage

For storage of the system when not in use, disconnect the power cord and store it inside the cart. Stow the handpiece in its compartment behind the upper door and the footswitch in its compartment behind the lower door. Remove all loose objects from the work surfaces. Close the notebook computer and consider removing it to a secure location. Wipe the surfaces with a soft cloth. Apply the brakes to the front casters to keep it in place.

Transport

The system is designed to be transportable, both within and between hospitals, clinics and offices.

Note: The system has no internal power supply (no battery) to support image acquisition while disconnected from a wall outlet. (The notebook computer can operate using its own battery.)

To relocate the system within a building:

1. Power down the system through the software by selecting and then **Shutdown**.
2. Switch OFF mains power on the back of the unit. Unplug the power cord from the wall outlet and drape it over the transport handle.
3. Secure the handpiece in its holster or inside the storage compartment.
4. Unlock the caster brakes.

Now you can gently roll the system on all four casters to the new location. Move the system slowly to minimize vibration. Once in the new location, apply the caster brakes, plug in the power cord and restart the system.

To transport the system to another location:

1. Power down the system through the software by selecting and then **Shutdown**.
2. Switch OFF mains power on the back of the unit. Unplug the power cord from the wall outlet and drape it over the transport handle or store the power cord inside the cart.

3. Carefully remove the lens and store it in the lens box. Secure the handpiece and footswitch in their storage compartments in the cart.

Figure 4 Transporting the Shuttle

4. Remove the notebook computer from the work surface and carry it separately.

5. Close the cart doors. Unlock the caster brakes.

6. Extend the transport handle upward and use it to tilt the cart and roll it to a vehicle for transport.

Inside the vehicle, we recommend that you lay the RetCam Shuttle front side up.

Electrical Safety Information

The system has been designed, inspected and tested to comply with the safety requirements of IEC60601-1 with respect to fire, shock and mechanical hazards only if used as intended.

Class I Type BF Electrical Equipment

Rated for Continuous Operation

IEC 60601-1:1995

Accessories equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC6950 for data processing equipment and IEC 60601-1-1 for medical equipment.) Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible to ensure the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, contact Clarity service.

WARNING: This equipment should be connected using the power cord supplied by Clarity.

WARNING: To avoid risk of electric shock, this equipment must be connected to a supply mains with protective earth.

Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
Radiated Emissions CISPR 11/ EN 55011	Class A 30 MHz to 1 GHz	The RetCam system uses RF energy for its internal function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	Class A	The RetCam system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by health care professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Immunity Test Summary

Test Type	Test and Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	The RetCam Portable requires ESD exemption. See Important User Safety Notices.
Electrical Fast Transients/burst EN 61000-4-4	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 0.5, 1 kV Line to Line ± 0.5, 1, 2 kV Line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interruptions EN 61000-4-11	>95%, 0.5 Cycles 60%, 5 Cycles 30%, 25 Cycles >95%, 250 Cycles	If the user of the RetCam system requires continued operation during power mains interruptions, it is recommended that the RetCam system be powered from an uninterruptable power supply (UPS).
Power Frequency (50/60) Hz magnetic field EN 61000-4-8	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test Summary

Test Type	Test and Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	0.15-80 MHz, 3Vrms, 80% 1 KHZ AM	Portable and mobile RF communications equipment should be used no closer to any part of the RetCam system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d= (3.5/ E1)x(square root of P) 80 MHz to 800 MHz d= (7 /E1)x(square root of P) 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). E1 is 3 V/m Conducted Immunity: d= (3.5/ V1)x(square root of P) where V1 is 3 Vrms Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Radiated Immunity EN 61000-4-3	80MHz-2.5GHz 3V/m 80%@1kHz	
Magnetic Immunity EN 61000-4-8	3A/m 50/60 Hz	Video display terminals and other electron beam devices (e.g. X-ray image intensifiers) may use a justification for lower IMMUNITY COMPLIANCE LEVELS as allowed by 36.202.1 a).

WARNING: Interference may occur in the vicinity of equipment marked with this symbol.  This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.

- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Note: The notebook computer, Hewlett Packard Model 6730B has met all requirements of EN55024 (IT Equipment Immunity Requirements) and IEC 60601-1-1, General Requirements for Safety Collateral Standard: Electromagnetic Compatibility Requirements and Tests. However, this notebook computer does not fully meet Clause 36-202-2 of IEC 60601-1-2. Refer to the Electromagnetic Environment Guidance section in the "Immunity Test Summary" on page 17.

Important User Safety Notices

1. Before moving the system to a new site, carefully remove the lens from the handpiece and store it in the case. Store the handpiece in the cart.
2. Never contact the front of the lens piece with hard or sharp objects. This could damage the precision optics and sealing.
3. DO NOT AUTOCLAVE any part of the device.
4. Appropriately power down and unplug the unit and allow the illumination bulb to cool before replacing it.
5. Newly acquired data may be lost if power is interrupted during live imaging.
6. The system comes protected from viruses, worms, and spyware with Microsoft's anti-malware. Please refer to your warranty prior to adding any additional software or contact Clarity Service.
7. It is possible during the connection of any cable or device into any of the Notebook computer ports the computer may lock up. This is an indication that a source of High Electrostatic Discharge (+/-6 Kv) was discharged into one of the ports of the computer. If this should occur, please reset the Notebook computer's power. To perform a system reset, press the power ON button on the Notebook computer for a few seconds until the system powers down, then press the power button ON again to power the Notebook back ON. This does not present a safety risk to the patient, user, or environment.

Labels and Symbols

Focus Controls

Intensity Controls

SNAP (capture) switch

Read instructions

Caution:
Do not look directly into light source

Protective earth (ground)

Alternating current (AC)

System contains fuse of indicated type.
Do not use any other type.

Non-ionizing electromagnetic radiation

Read accompanying user documentation

Fragile contents

This side of carton up

Temperature limits

Authorized representative in the EU

Type BF equipment (applied part is handpiece)

To prevent damage to lens piece, carefully store handpiece in holster when not in use.

Clean lens piece after use

Separate collection of waste at end-of-life as required by European directives. Contact Clarity for equipment disposal instructions.

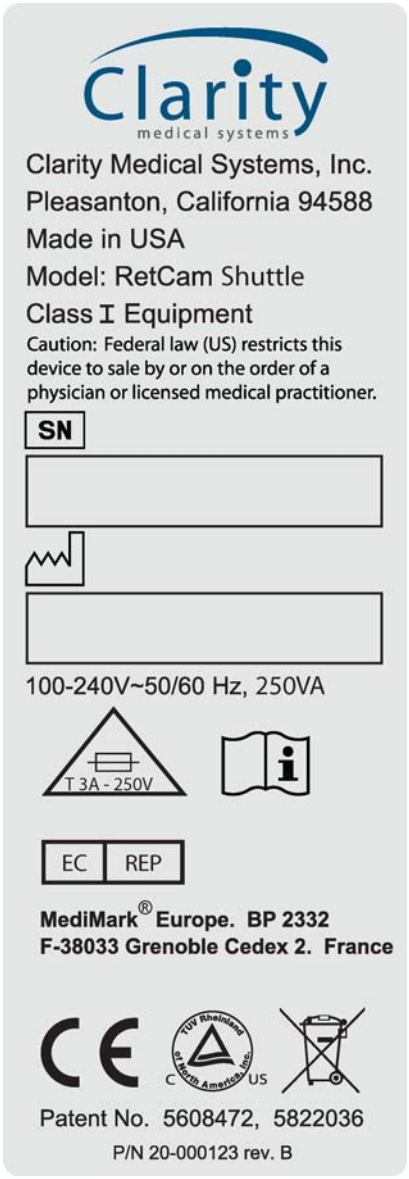
European conformity

North American compliance certification

Serial number

Manufacturer

Label


Clarity
medical systems
Clarity Medical Systems, Inc.
Pleasanton, California 94588
Made in USA
Model: RetCam Shuttle
Class I Equipment
Caution: Federal law (US) restricts this device to sale by or on the order of a physician or licensed medical practitioner.
SN
100-240V~50/60 Hz, 250VA
T 3A - 250V
EC REP
MediMark® Europe. BP 2332
F-38033 Grenoble Cedex 2. France
Patent No. 5608472, 5822036
P/N 20-000123 rev. B

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2 System Functions

This section addresses system level attributes and functions that are important to understand for general operating purposes, including:

Figure 5 Main power switch

Power Cord and Power Connector

The main power switch is located above the power cord inlet. It must be in the ON position to operate the system.

Shown OFF

Note: Do not switch OFF or disconnect main power during imaging as data corruption may occur.

Turning ON the RetCam System

1. Connect the notebook computer to the notebook power supply cable and the USB video input cable (unless already connected).

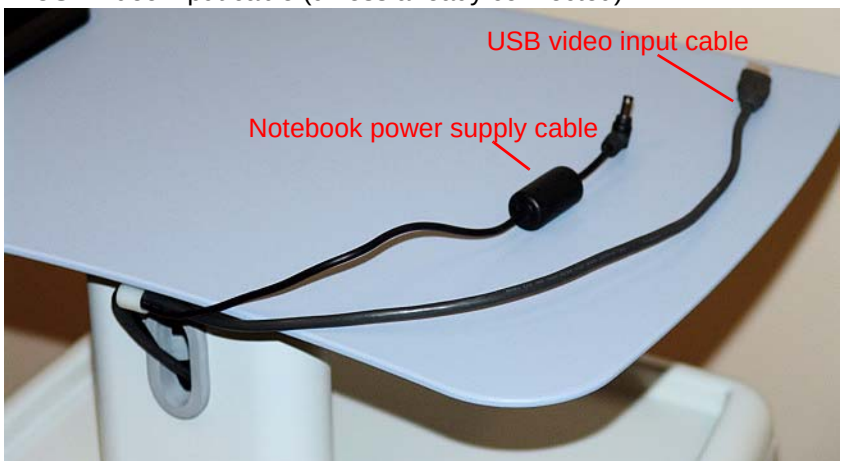

Figure 6 Computer power and USB (video) cables

2. Switch power ON in the EO box (unless already ON).

Figure 7 EO box

3. Plug the main power cord from the system into a properly grounded hospital grade electrical outlet. Turn ON main power. The software should start automatically. If not, power ON the notebook computer. The system is ready when you see the message “No Patients to Display” or “Not Displaying Patients.”

Turning OFF the RetCam System

Note: We strongly suggest that you backup and store your data prior to turning OFF the system.

1. Select the red shutdown icon at the bottom right corner of the screen.

2. Select “Shutdown.”

Note: If the computer hangs, wait at least one minute to make sure that the system is not busy. If the system is still not responding, press the power ON button on the Notebook computer for 3-5 seconds until the system powers down. Select Shutdown Computer.

Using Hard Shutdown

WARNING: Do not use the hard shutdown method unless necessary because data corruption can occur.

1. Press the power ON button on the Notebook computer for 3-5 seconds until the system powers down.
2. Turn OFF main power switch on the back of the unit or unplug the power cord from the outlet.

Turning Off for Extended Periods

If you are not going to use the system for an extended period (such as one day or more), it is advisable to switch OFF the EO box only. This will help preserve the illumination lamp.

Note: These actions will remove power from the entire system except the notebook computer.

The Electro-Optical Box (EO Box)

The EO box is akin to the central nervous system of the RetCam, receiving your input from the footswitch and camera, and directing its output to camera, computer and notebook display. It contains the illumination lamp and light intensity controllers, focus, camera and footswitch controllers, and passes live images from the camera to the screen. This section introduces its components and functions you can control with it.

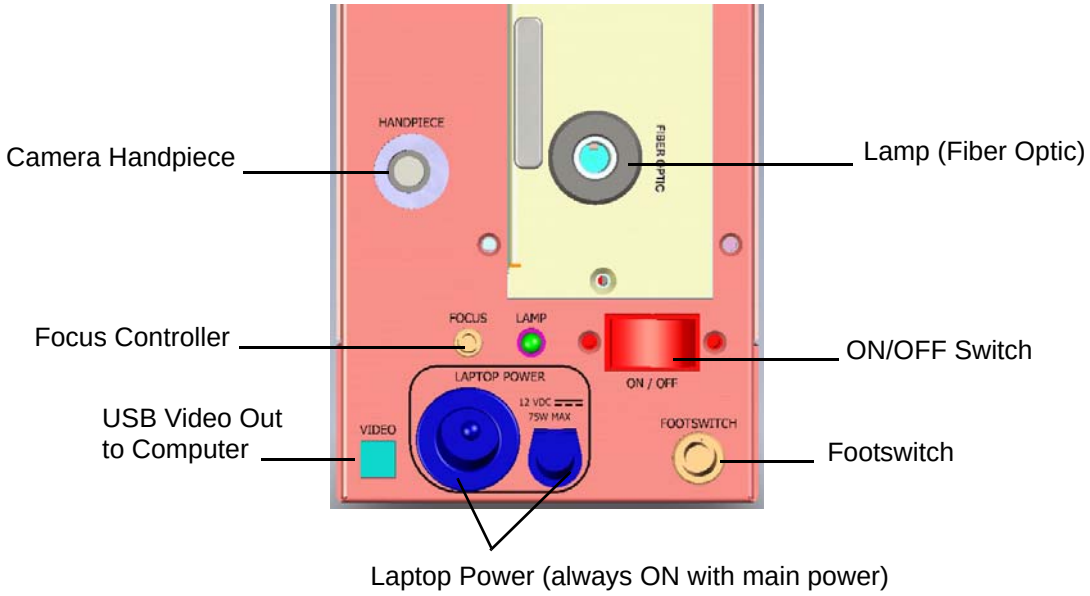

Figure 8 EO box drawing (lower portion) showing connectors

Note: It is not necessary to remove any of the connectors for use, storage or transportation.

WARNING: Do not remove any connections while the system is powered ON. The main power switch must be OFF prior to connecting or disconnecting any cables from the EO box.

The **Lamp (Fiber Optic)** connector is a receptacle for insertion of the handpiece fiber optic line, which is part of the camera interconnect cable.

WARNING: Do not look directly into the Lamp (Fiber Optic) opening when the EO box is ON.

The **Focus** controller is a direct insert receptacle for insertion of the (white) focus motor cable, which is part of the camera interconnect cable.*

- Insert/Detach: Align the red dot on the connector with the red dot on the Focus port and insert. To detach, pull back on the connector, but not the wire. The focus connector is not threaded!

The **Camera Handpiece** connector is a receptacle for insertion of the black camera controller cable, which is part of the camera interconnect cable.*

- Insert/Detach: To insert, align the slot in the port with the pin on the connector, insert and screw in clockwise to secure. To detach, unscrew (counterclockwise) the connector sleeve and pull out.

Lens Installation

The diagram below illustrates how to install all lens pieces. The instructions are also repeated below.

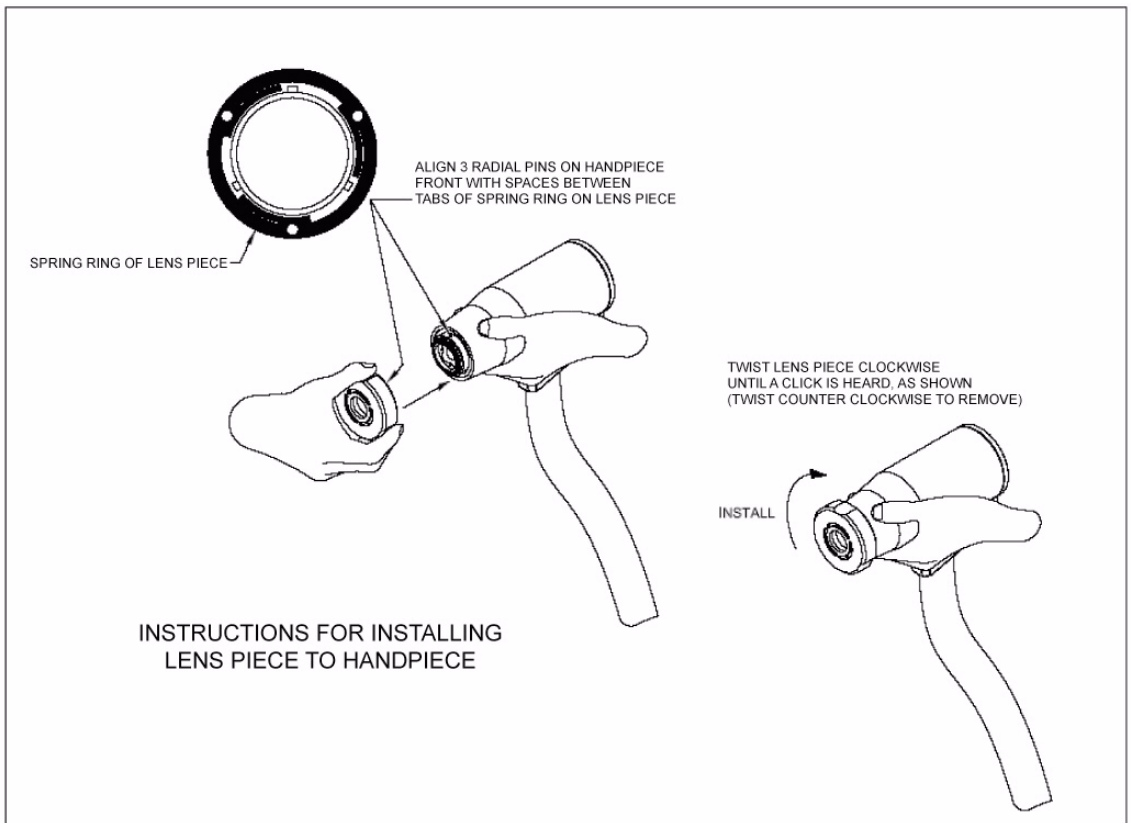

Figure 9 Instructions for installing a lens piece to the handpiece

Instructions for Installation of All Lens Pieces

1. Fit the lens piece on the handpiece, aligning the 3 radial pins on the front of the handpiece with the spaces between the tabs of the spring ring on the lens piece.
2. Twist the lens piece clockwise (as shown) until you hear a click, indicating that the lens piece is locked in place.

WARNING: Always inspect the lens before use for damage such as chips, cracks or roughness that could injure the patient's eye.

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3 Using the RetCam System

Managing Patient Records

This section describes how to add a new patient and locate the records for an existing patient.

The software is ready to use when you see the **Start Screen** shown in Figure 10.

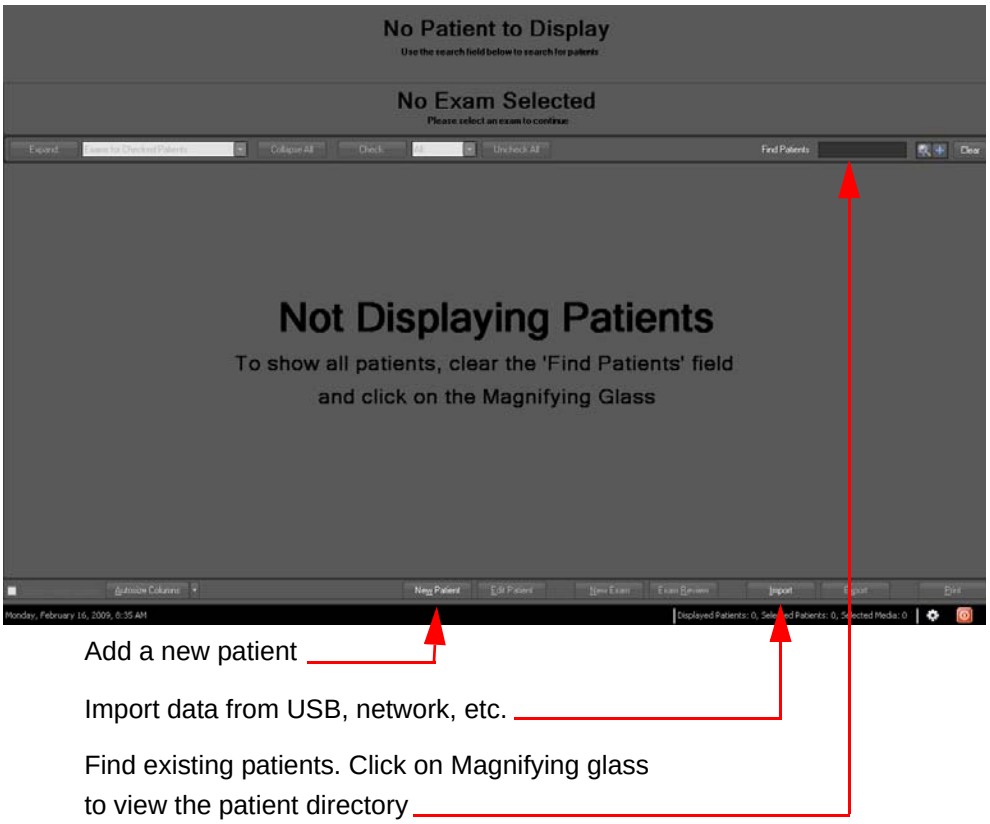


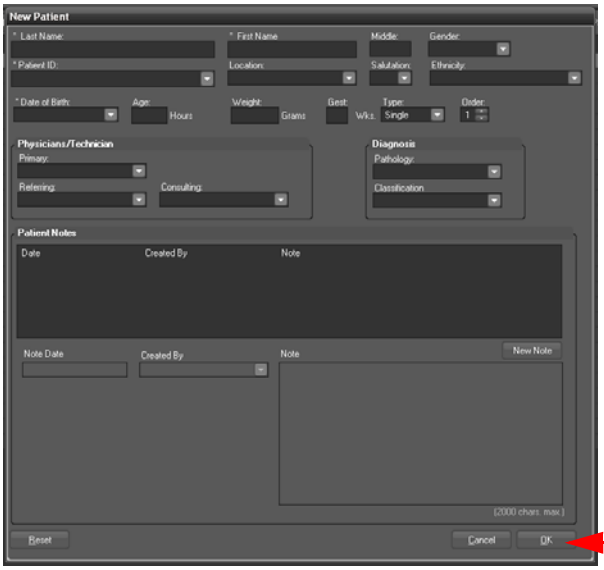
Figure 10 Start screen

Add a New Patient Record

To create a new patient record, the following information is required:

- First Name
- Last Name
- Date of Birth
- Patient ID

Patient information is repeated in several of the screens. The patient name and Patient ID are always shown in the upper left corner of every screen.



Select OK to proceed.

Enter information manually or use menus, where available.

Figure 11 Add new patient screen

Editing a Patient Record

Highlight the patient's record from the Patients and Exams screen.

Select Edit.

You can edit the following information:

- First Name
- Last Name
- Gender (Male, Female, Other, or Unknown)
- Date of Birth
- Weight (in grams)

Note: Any fields on the Edit Patient Screen are editable.

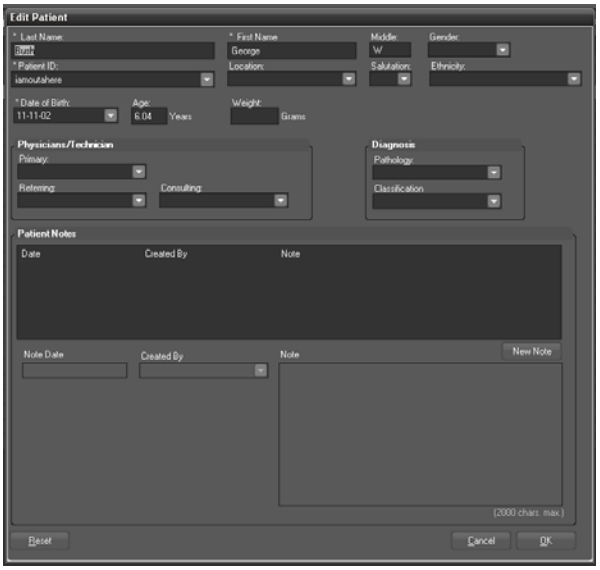


Figure 12 Edit patient record screen

Finding Existing Patient Records

You can search the directory to locate specific patient records.

Figure 13 Search buttons

From the Start screen, select the  icon to display the entire patient directory or select the plus sign  to locate patient records using one or more of the search features (see Figure 14).

Figure 14 Patient search options

Select **Clear** to clear all search fields.

Search Results

When you select the  to display the entire patient directory, the results are displayed as shown in Figure 15.

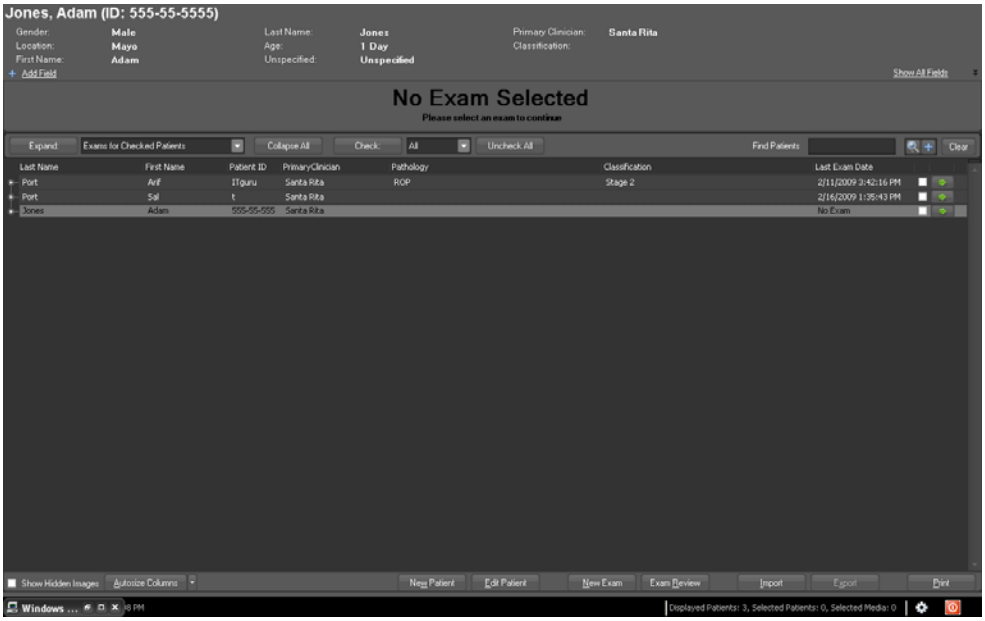


Figure 15 Patients and Exams Screen (Patient Directory)

From the **Patients and Exams Screen**, you can use the buttons shown in Figure 16 to sort the results.

Figure 16 Patients and Exams screen navigation buttons

Performing Exams

You can use the RetCam system to capture still images or video after selecting a patient. Select the green arrow on the right side of a patient name, or select the New Exam button. To start an exam, you can select a Preset Configuration, which can be easily edited, or Manual Configuration.

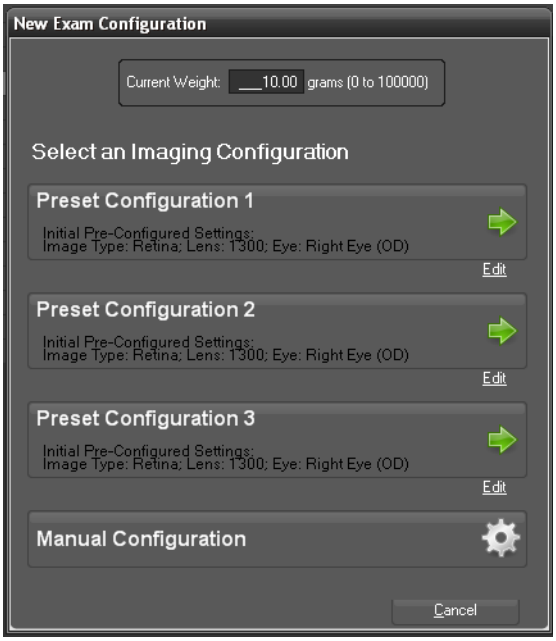


Figure 17 New Exam configuration screen

The following Information can be defined in the Preset or Manual Configuration:

Image Type	Lens	Eye
Retina	300	Right (OD)
	800	Left (OS)
Anterior Segment	1200	Unspecified
Unspecified	1300	
	Unspecified	

Once the new exam is configured, select the green arrow to the right to enter the New Exam screen.

Capturing Still Images

In the New Exam screen, you can add the name of the Imaging Technician in the upper right corner of the screen.

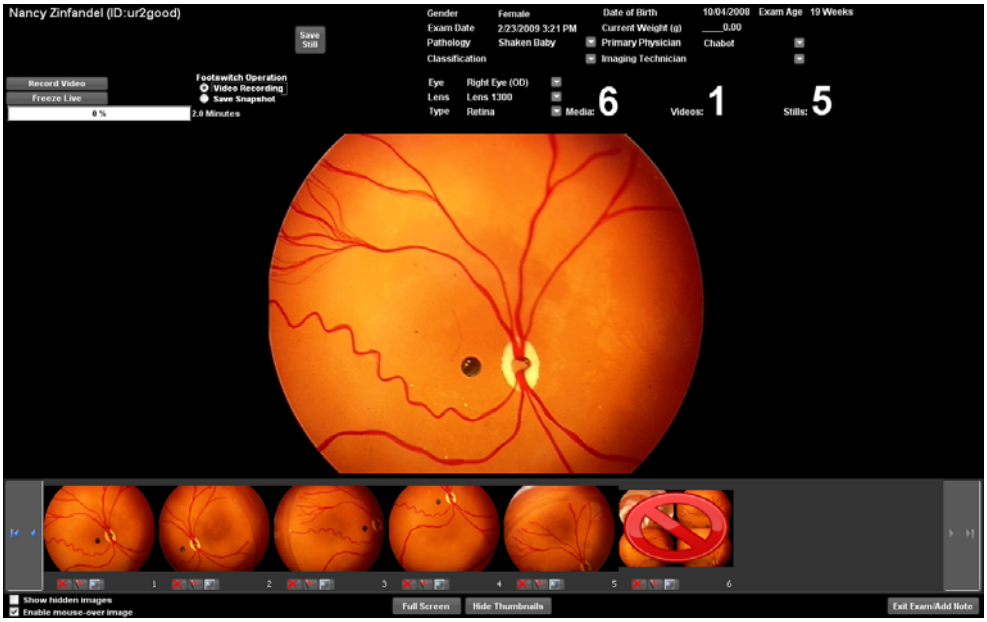


Figure 18 Still image screen

1. Set the Footswitch Operation to Save Snapshot (default).

2. Adjust the focus and light intensity using the footswitch.
3. Depress the green SNAP button to capture a still image. You can also capture an image using the "S" key on the Notebook keyboard or by selecting the Save Still button.
4. The saved image appears in your thumbnail display (if the "show thumbnails" option is enabled).

Capturing Video

1. Set the Footswitch Operation to Video Recording.

2. Adjust the Focus and Light Intensity using the footswitch.
3. Depress the green SNAP button to Start and Pause video recording. The progress bar will display the amount of video recorded. You can also depress the spacebar on the Notebook computer to Start and Pause Recording.

Note: You can capture still images by depressing the Save Still button during video recording.

4. Select the Stop Recording button to STOP recording video.

5. A 2 by 2 block of pictures appears in your thumbnail (if the "show thumbnails" option is enabled). The video is automatically marked for deletion.
6. To save the video, deselect the red X below the video thumbnail.

Figure 19 Deselect the red X to save video

Note: The storage capacity of the system hard drive is a maximum of approximately 100,000 still images or a maximum of 140 minutes of total video (for example, 70 videos of 2 minutes duration each or 280 videos of 30 seconds each). Saving a combination of videos and stills will affect the total number of each that can be saved. Saving images with annotations reduces the total number of images that can be saved.

Recommended Procedure

Because saving video consumes a great deal of disc space, to maintain optimal system performance we recommend that you capture video of the entire exam, save stills from the video, and delete the video. To do this:

1. Capture video (see Capturing Video) but DO NOT SAVE the video. Instead double click the video in the thumbnail display (the hover over image feature must be disabled) to go to the Review Screen.
2. In the Review Screen, use the video playback features to replay the video and

.

3. Select this button to return to the New Exam screen.

Figure 20 Video playback controls

4. In the New Exam Screen, the viewed video is marked for deletion (unless you saved the video as shown in Figure 19). View the exam thumbnails and select any other images for deletion.

Video Playback

Video playback buttons are:


Reverse, pause, and play


Fast forward


Go to the beginning of the recorded video


Go back one video


Advance one video


Go to the end of the recorded video

Control the rate of playback or search.

Use the buttons or the scrollbar to locate images of interest.

Figure 21 Video controls and scrollbar

Tip: Using the left and right arrow keys on the keyboard will also move the video back or forward one frame at a time.

Using Helpful Features

The RetCam software includes some useful features to streamline your work.

Shortcut Keys

An underlined letter indicates a quick key. To use a quick key, press ALT and the letter key simultaneously.

Note: Do not use Windows shortcut keys, for example Copy (Ctrl+C), Paste (Ctrl+V), Undo (Ctrl+Z), and others.

Use the playback controls at the top of the screen to locate a still image:

- Start playback by selecting **Play**  or **Reverse**  **.**
- Select **Pause**  when you see an image you want to save.
- Select **Save Still** (or press **'S'** on the keyboard or press the **Snap** button on the footswitch).

Changing Image Capture Options During an Exam

Before you start imaging, verify that the options displayed for eye, image type and lens piece are correct. If necessary, you can edit options from the image capture screen.

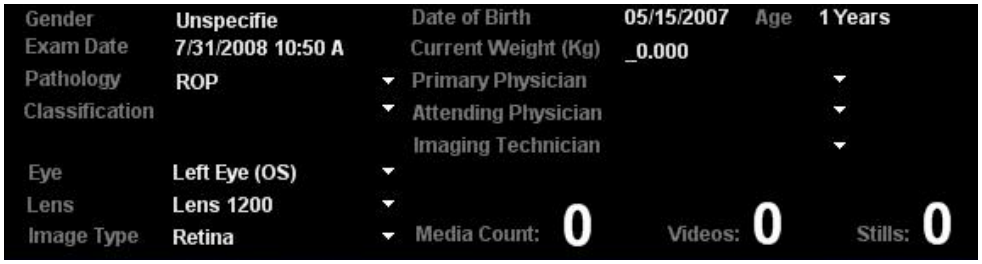


Figure 22 Select options for image capture

Eye Changing: Right Eye (OD) / Left Eye (OS)

To image the other eye in the same session, expand the **Eye** menu and select the other eye (**Right Eye (OD)** or **Left Eye (OS)**). The **Eye** selection is saved with the image.

Note: When using this option, be careful that you select the correct eye before you save the image. This is especially important when both eyes are captured in one video clip, and you save still images from the video. Make sure you select the correct eye before you save each still image from the video.

Note: Images and video can be selected for deletion only during the imaging session. Once the session has been exited, the images will be saved for that session.

Lens Changing Lens

You can also select a different lens piece during imaging. Expand the **Lens** menu to select **1300** (Premature Infant), **1200** (Standard Baby), **800** (Posterior), **300** (High Mag), or **Unspecified**. The lens piece selection is saved with the image.

Image Type Changing Image Type

Expand the **Image Type** menu to select **Retina, Anterior Segment,** or **Other** during an imaging session. All selections record the images in color. The Image type selection is saved with the image.

WARNING: System power from a fully-charged battery is available for at least 15 minutes after an AC (main) power loss. In the event of an AC power loss, we strongly suggest that you complete the imaging session and save images to prevent potential data loss. Start a new live imaging session only after reconnecting the AC power.

Enable mouse-over image preview: When hovering over thumbnail images, a larger image will appear. By default, this feature is selected on and may be turned off.

Figure 23 Enable mouse-over

Adding Exam Notes

When you select the **Exit Exam/Add Note** button at the bottom right corner of the image capture screen, the Exam Notes dialog appears. For each eye, it provides a field where you can type in notes.

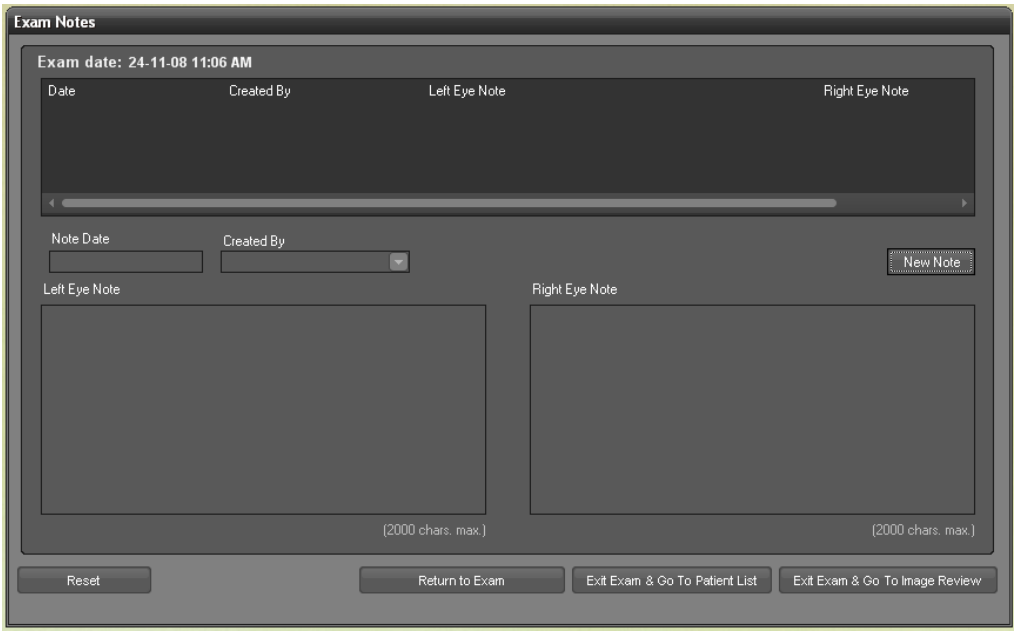


Figure 24 Exam Notes dialog

To add notes:

1. Select **New Note** to activate the notes fields.
2. Input **Created By** information.
3. Type new notes in the fields titled Left Eye Note and Right Eye Note.
4. Select **Save Note** to add notes you have typed to the notes above.

Note: You cannot change a note after you select Save Note.

- Select **Reset** to clear all fields.
- Select **Return to Exam** to save note and return to Live Imaging.

- Select **Exit Exam & Go to Patient List** to save note and return to the Patients and Exams screen.
- Select **Exit Exam & Go to Image Review** to save note and return to the image review screen.

You can add notes also from the Review screen. Once saved, the text cannot be modified. You can append text to notes from the Review, Compare, and Image Process screens by selecting **Exam Notes**. Notes are identified by date/time and person creating the note.

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4 Image Review and Compare Mode

Having acquired images, they are available for review and comparison This section covers the following topics:

Image Review Screen

The Image Review screen appears optionally when you exit live imaging. You can also access it by selecting the Exam Review button on the Patients and Exams screen.

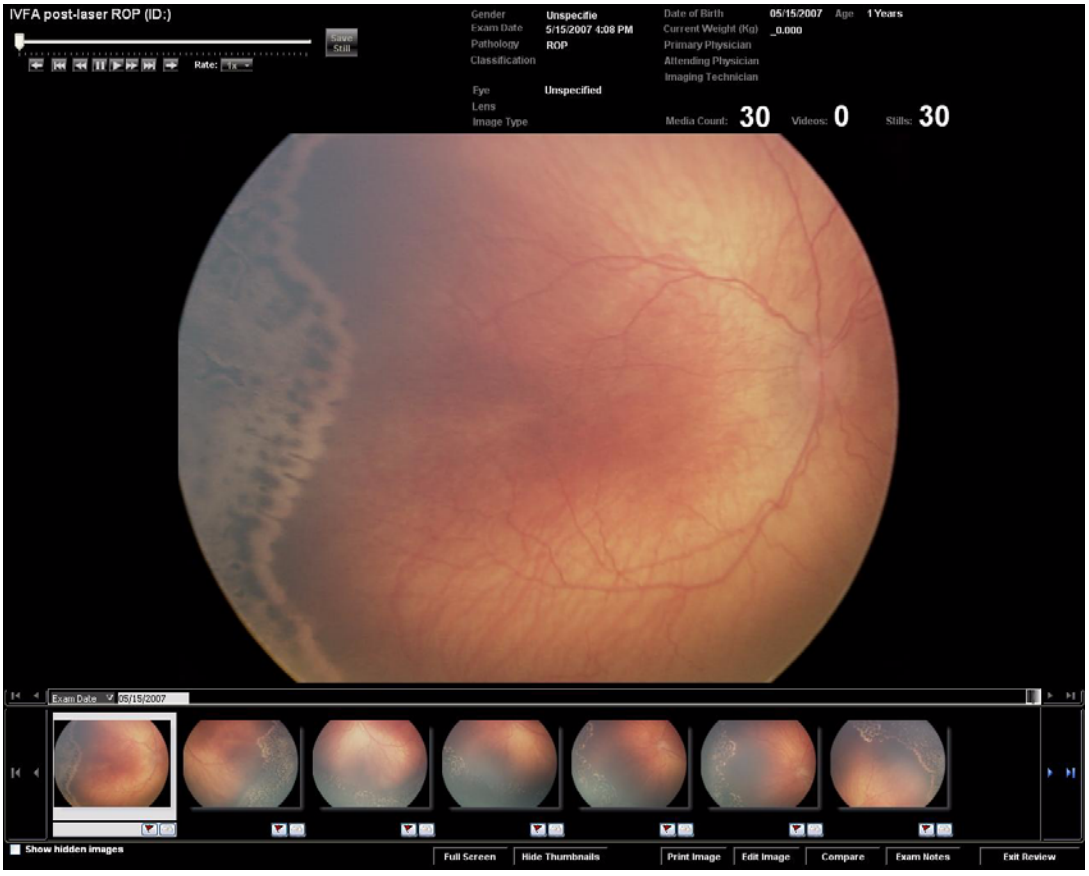


Figure 25 Image Review screen

The Image Review screen displays the images acquired in the session just completed. When you access the Image Review Screen by other means, it displays the images for the last patient and session you selected. To review exams for a different patient, exit to the Patients and Exams screen, and select another patient.

By default, thumbnails for all images acquired in the selected session appear along the bottom of the screen.

Video playback controls appear in the upper left corner of the screen.

The currently selected image (the first one by default) appears full size. Select a thumbnail to display the full resolution image. You can use the arrows at the left  and right  edges of the thumbnail strip or the up and down arrow keys on the keyboard to scroll through the thumbnails or select a thumbnail.

Thumbnails of video clips show four images (first, last, and two intermediate images in the video) in the quadrants of a square.

Click on the thumbnail to bring the video to the display area. Use the video playback buttons to control the video. The buttons have the same functions as for live imaging. Click **Play**  to start playing video.

The following options are available on the Review Screen:

Exam Date 

Select a different exam to review by clicking the arrow  next to **Exam Date**.

Show Hidden Images

Default is unchecked, in which case only thumbnails of non-hidden images are displayed. When this box is checked, thumbnails for hidden images appear and are available for full size viewing.

Hide Image

Click the **Hide Image** icon  below the highlighted thumbnail to hide the current image. You can click this icon beneath any thumbnail to hide that image. You can use the icon to toggle between hidden  and unhidden  . Hidden items are not deleted. Their thumbnails do not appear unless the **Show hidden images** box is checked.

Unhide Item

When **Show hidden images** is checked, select the **Hide Image** icon  to unhide an image. The hidden image icon appears in the upper right corner of the thumbnail for a hidden image.

Flag Image

Click the **Flag Image** icon  to flag the current image as an image of special interest. A small red flag appears at the top left corner of the thumbnail. To unflag an image, click the icon again. The icon toggles between flagged and unflagged.

Full Screen

Click **Full Screen** to display a full screen view of the current image, with no thumbnails visible.

Hide Thumbnails

Click **Hide Thumbnails** to remove the thumbnail display without changing the display of the current image.

Print Image

Click **Print Image** to print the current image displayed.

Edit Image

Click **Edit Image** to edit the current image.

Compare

Click **Compare** to view two images side-by-side on the screen. See Compare Mode for details.

Exam Notes

Click **Exam Notes** to review or append text to the session notes in the Review screen. You cannot alter saved notes. Notes are identified by date and created by.

Exit Review

Click **Exit Review** to exit the current review session and return to the Patients and Exams screen.

Compare Mode

The Compare screen appears when you click **Compare**. Use the Compare screen to compare any two images. You can compare images for one or more exams for a single patient.

.

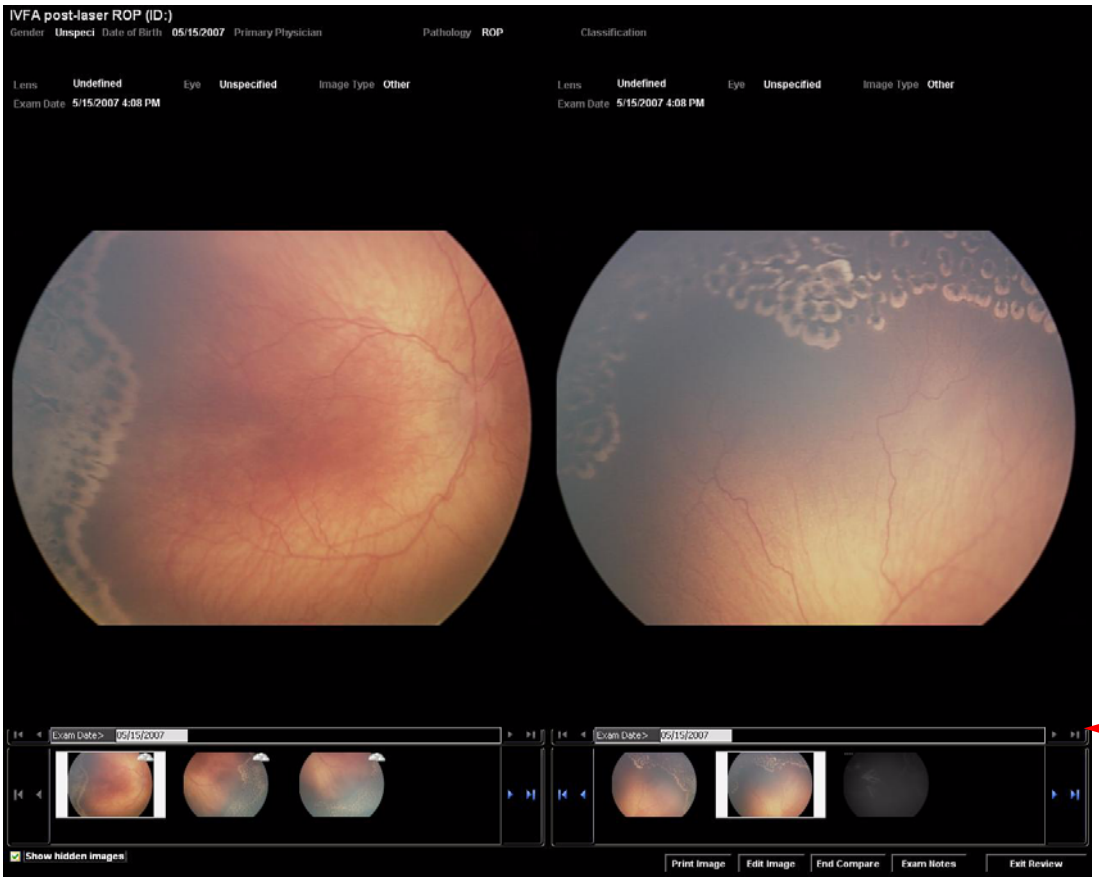


Figure 26 Compare [Images] screen

The last image displayed on the Image Review screen will appear on the left side of the Compare screen. On the right side, by default, the first image of the first session for the same patient appears. Identifying information for each image appears above it. Below each image at the bottom, thumbnails appear for all images in the same session. The Exam Selector displays the dates for all the current patient's exams above the thumbnails. The highlighted date is the exam date for the current thumbnails. To view images from a different exam, select another exam date from the Exam Selector.

The video playback controls are not displayed on this screen because It is not possible to compare videos.

The Compare screen provides a toolbar for the following options:

Show hidden images

The check box for displaying hidden images is available.

Print Image

Click **Print Image** to print the two images displayed on this screen, one above the other.

Edit Image

Click Edit Image to display the Image Adjustment window.

End Compare

Click **End Compare** to return to the display of a single image.

Exam Notes

Click **Exam Notes** to review or append text to the exam notes for that image. You cannot alter saved notes. Notes are identified by date/time and person creating the note.

Exit Review

Click **Exit Review** to return to the Patients and Exams screen.

Image Adjustment

To adjust an image, select the image from the Image Review screen and click **Edit Image**.

The Image Adjustment window appears. To exit the Image Adjustment window, click the “X” in the upper right corner of the window.

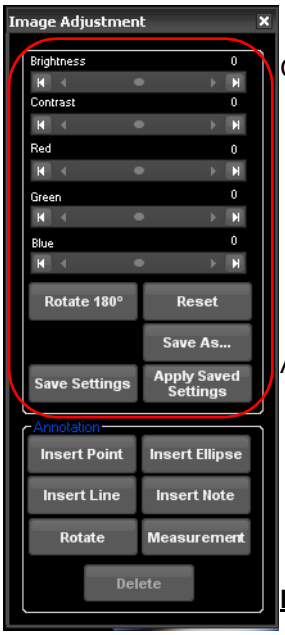


Image Adjustment Parameters

Controls to adjust the image display parameters are:

- **Brightness**
- **Contrast**
- **Red**
- **Green**
- **Blue**

All parameters have a default setting of zero (0), and range from -100 to +100.

- Each click on the right or left arrow at the end of the slider bar changes the parameter value by 1.
- Each click on the bar to the right or left of the slider changes the parameter to the end of the range.

Rotate 180º

Click this button to rotate the image 180º.

Reset Button

Click **Reset** to reset all display parameters to zero.

Save As

Select to export the image.

Save Settings

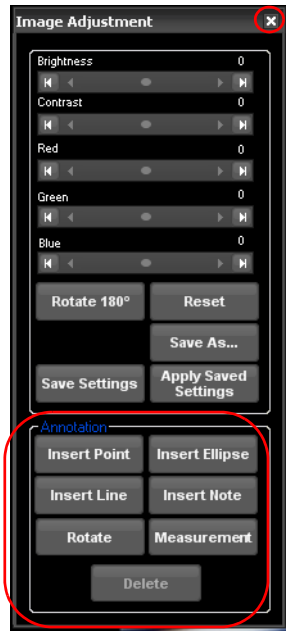
Click to save the current settings for **Brightness, Contrast** and **Red, Green** and **Blue**. The saved settings can be applied when you select **Apply Saved Settings**.

Apply Saved Settings

Click to apply the currently saved settings for **Brightness, Contrast** and **Red, Green and Blue**. Image display adjustments are applied to all images in the current image processing session, until you save new settings or click the **Reset** button, which resets all parameters to zero.

When you leave the current session, the display settings are reset to zero.

Note: Images you save from the Image Adjustment window will reflect image display adjustments (and all other changes) you make, but the original images in the database will not be changed.



Annotation

You can annotate an image by inserting graphic elements or text notes.

Click to select any of the following annotation features:

- Insert Point—Insert pointer and text on the image.
- Insert Ellipse—Draw an ellipse on the image.
- Insert Line—Draw a line on the image.
- Insert Note—Add text to the image.
- Rotate—Rotate the pointer.
- Measurement—Display the number of pixels between two points.
- Delete—Remove a selected annotation.

Select the “X” at the top right to close the screen.

Note: The original images in the database are never changed, even when you modify the image displayed on the screen. You can save processed images only outside the RetCam database and in a non-proprietary format.

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5 Import and Export Images

You can import or export images:

- To make RetCam data available on other RetCam stations, which include RetCam 3 and RetCam II systems, and PCs running RetCam Review Software.
- To make a backup copy of the original image data kept on the hard drive.
- To view with standard image software.
- To use RetCam images with third party imaging systems.

Backing Up Images

The RetCam system stores all images to the local hard drive. It is highly recommended to create a central repository on a network of all data from the RetCam device for long term data backup.

Recommended Backup Frequency: Each day you acquire new images.

Exporting Images

You can export data to any accessible location. There are three general steps to complete export. These are:

1. Select Images for Export, below
2. Select Export Options, page 46
3. File name format menu, page 48

Select Images for Export

1. Go to the **Patients and Exams Screen** and check the box next to each image for export. You can also use the automatic Expand and Check box features located in the upper menu.

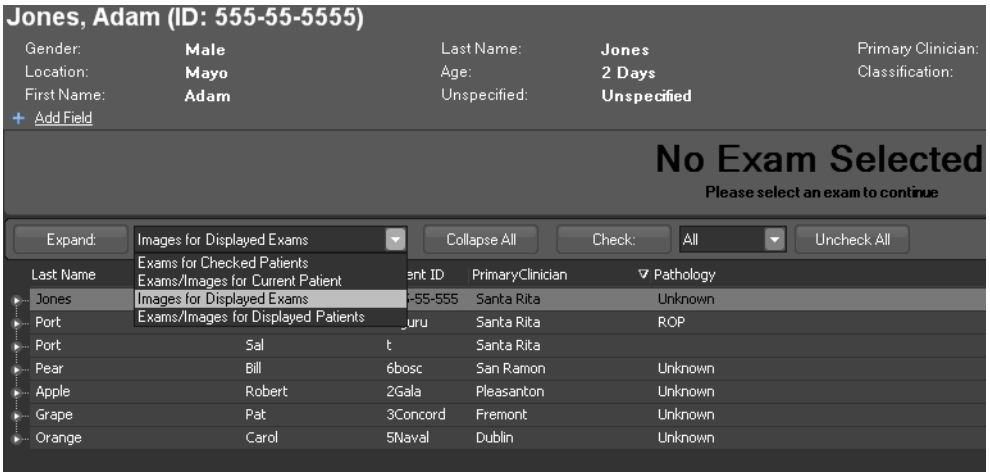

Figure 27 Select patients and exams for export

2. Select the Export button on the lower menu.

3. The Export dialog appears.

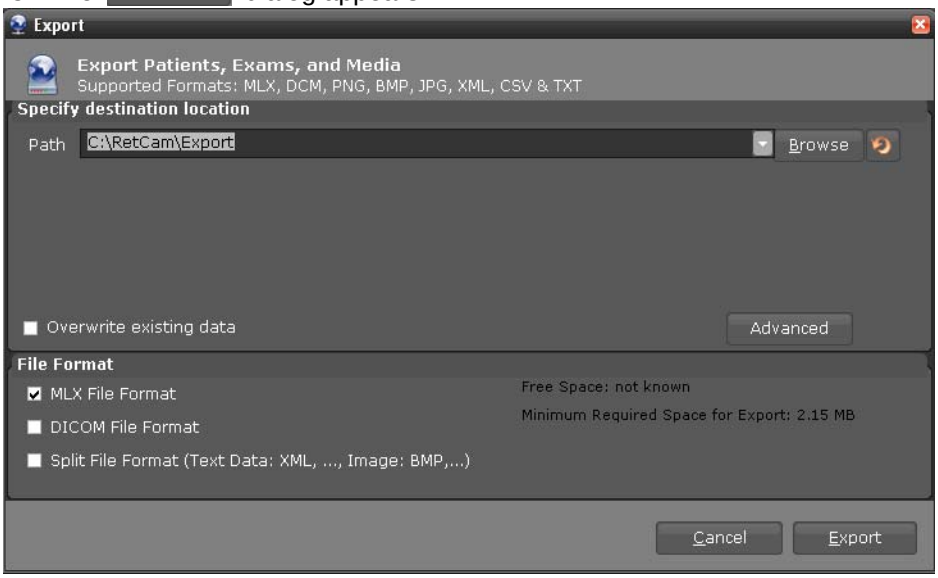

Figure 28 Export dialog

By default, the dialog shows the last destination location path used.

Note: The Minimum Required Space for Export is displayed. Verify that the export destination has sufficient free space to accept the exported files.

Note Regarding File Size Capacity: We recommend that you do not export more than 2000 images in one batch, because the export will take a long time. We recommend that multiple smaller transfers be executed.

Select Export Options

1. To change the destination location path, select Browse. Selecting the red reverse arrow resets the source location to the default setting.

Figure 29 Export dialog showing closeup of destination

2. Select **Overwrite existing data**. This optional feature is useful if you are refreshing backup data:

3. Select File Format.

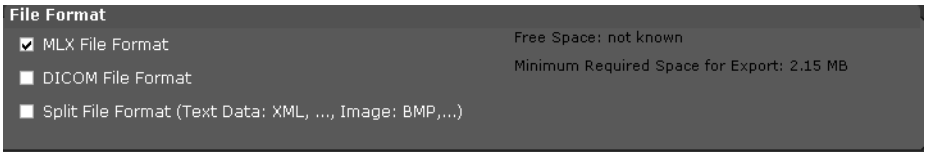

Figure 30 File format

Format Options

MLX	Clarity's proprietary encrypted data format
DICOM (DCM)	DCM is the filename extension for patient data files that are compatible with the DICOM (Digital Imaging and Communications in Medicine) standards for ophthalmology.
Split File Format	If you select this format, you will have additional options for the Export Image and Export Data features shown below.

Export Image Formats

PNG	Portable Network Graphic uses compression to reduce file size (about half the size of a bitmap file), but without loss in quality or resolution. It can be viewed in a standard web browser and used in image processing or viewing applications.
BMP	The bitmap format saves images at full resolution without any quality loss. It results in the largest files.
JPG	(or JPEG) This format uses compression to reduce file size, which results in loss of resolution or quality in proportion to the amount of compression. You can select the image quality before you save.

Export Data Formats

XML	Extensible markup language format
CSV	Comma separated values format
TXT	Generic text format

4. Select Advanced to display advanced features.

Select Advanced Options

The advanced features option allows you to:

- Create subfolders

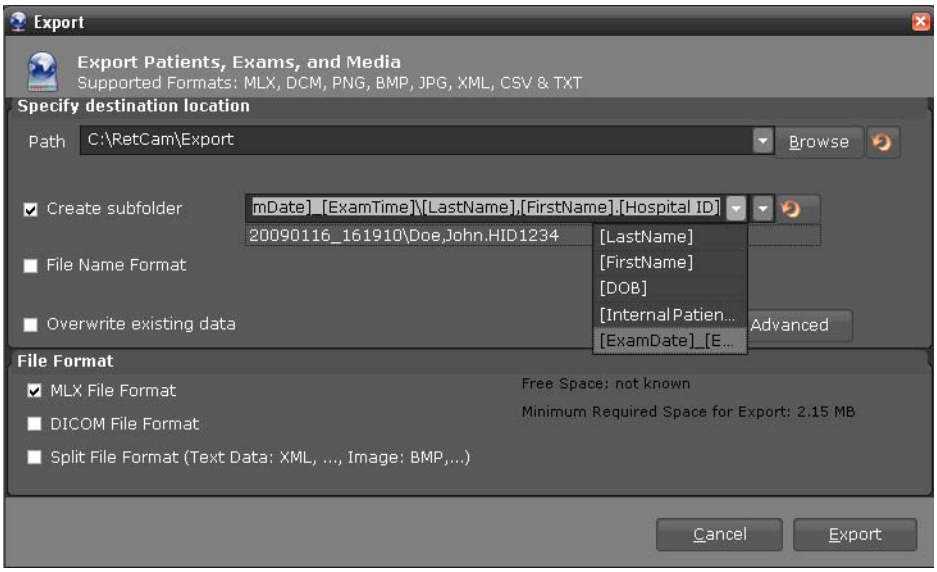

Figure 31 Create subfolders menu

- Choose a File Name Format

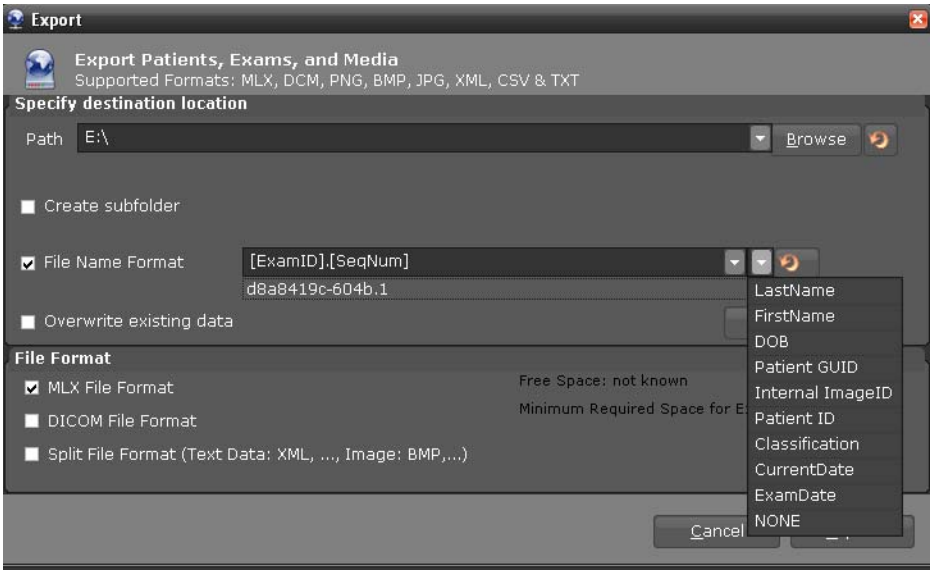

Figure 32 File name format menu

Complete Export

Select Export to initiate exporting or Cancel. A dialog opens to show export progress.

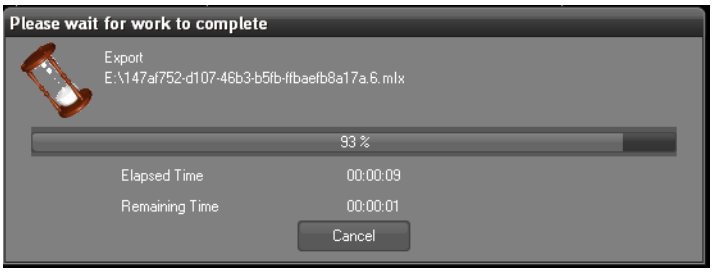

Figure 33 Export progress dialog

Importing Images

Except for data backup, the export destination on the network is an intermediate location. To complete the data transfer and make the images available for viewing on another RetCam system, you must use the RetCam software to import the transferred images into the target system database.

WARNING: Never connect the RetCam Shuttle to a network or any externally powered devices or peripherals *during imaging*.

Note: We recommend that you do not import more than 2000 images in one batch, because the import will take a long time. One way to limit batch size is to import only the files from which you (or someone else) exported a limited number of images. In general, we recommend you import images from one patient at a time.

Follow these steps to import RetCam images:

1. On the screen shown in Figure 34, select Import .

Figure 34 Start screen

The Import Folder dialog appears

.

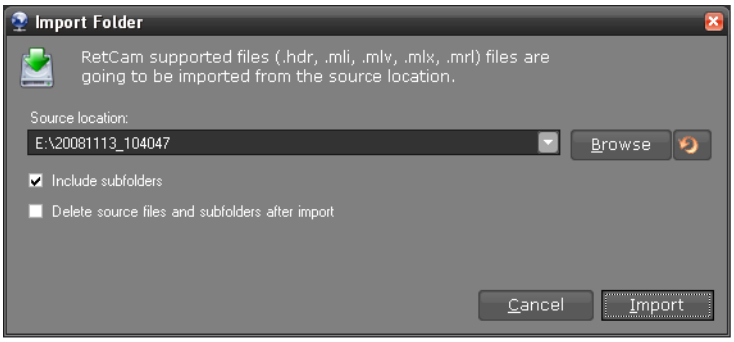

Figure 35 Import Folder dialog

By default, it shows the Source location path and all the options last used.

2. To change the source location, select the arrow to expand the path list or select **Browse**. Selecting the red reverse arrow resets the source location to the default setting.
3. Once the desired Source location is showing, you can select import options.
4. Select Import to initiate importing.
5. . A Select Import Data to save dialog will appear.

6. View imported data. Check **Selector** on the images or patient data you would like to import.

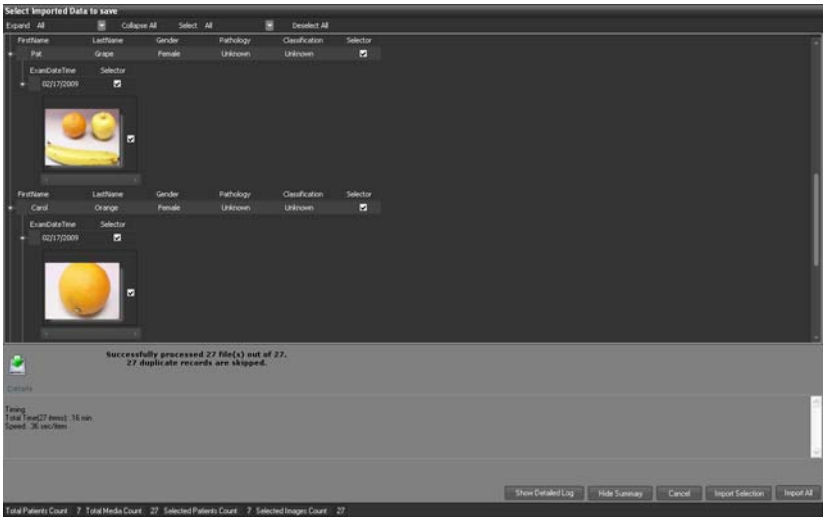

Figure 36 Select Import Data dialog

7. Select one of the options on the bottom menu.

Figure 37 Import options

Show Detailed Log	Provides details regarding the processed files selected for import.
Hide Summary	Hides Summary Information
Cancel	Cancel Importing
Import Selection	Allows importation of data only from checked items
Import All	Allows all processed files to be imported

The system will notify you when the import is completed.

Included subfolders check box

Select this check box if you want to import images in all subfolders of the source location. If not selected, you will import only the files found in the source location folder itself, and no images in its subfolders. To import files from a specific (patient) subfolder only, select that subfolder as the Source location.

Delete source files and subfolders after import check box

To manage the size of the export destination, select this check box to delete the source files and subfolders after import is complete.

Note: Do not select this check box if you or others want to import the same data to another RetCam station, which would be the case especially if you are importing from the backup repository.

Note: This does not affect any working RetCam database, but only the intermediate location where files are exported to and imported from.

8. Select Import to initiate importing, or Cancel . A dialog opens to show import progress.
9. A **Select Import Data to save** dialog will appear. If not all items were imported, you may select **Show Detailed Log** for the explanation. It could be because some files are duplicates (already in the destination database), or the file is not found, or it is corrupt, or the destination is write-protected.

   View imported data and select thumbnails you need to save. Select **Import Selection**. You can also select **Import All** to save all images.

   The system will notify you when the import is completed successfully.

6 Printing Images

The **Print** button appears at the lower right of screens when printing is available.

Note: Print is only available if there is a printer attached to the system, either directly or through the network, if so connected.

WARNING: Never connect the RetCam Shuttle to a network or any externally powered devices or peripherals *during imaging*.

You can **Print Images** from the:

- **Exam Review Screen**
- **Compare Screen**
- **Patient list (or Patients and Exams screen):** Print images, reports, or both

The default image size is 5" x 7." For optimal resolution, Clarity recommends printing images 5" x 7" or smaller. This also avoids the rapid depletion of printer ink.

Printing Images and Reports

You can print both images and reports from the patient list (or Patients and Exams screen):

1. Select (or highlight) patient.
2. Check the desired session, patient, or image.
3. Select **Print**.

The following dialog appears:

If you select this option for more than 100 images at a time, a warning message appears

Figure 38 Print dialog

Select the desired option(s).

- **Reports are formatted to fit on US letter size or A4 paper.**
- **Note: Network printers used with the system must have a printer driver supported by Windows XP.**
- **Note: Be aware that you must change the paper in the printer when switching between printing images and reports.**

See the User Preferences section for information on setting printer defaults.

7 User Preferences

The section describes the User Preferences available, including:

- System Identification/Institution
- Setting Pre-configuration Imaging defaults for New Exams
- Changing Date/Time
- Changing Speaker Volume
- Setting Printer defaults
- Setting Network connections

Select the cog icon in the lower right hand corner to access the User Preferences.

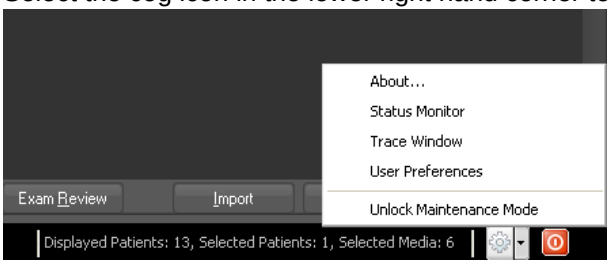

Figure 39 Access User Preferences

Select **About** to identify the RetCam software version. Select **OK** to exit.

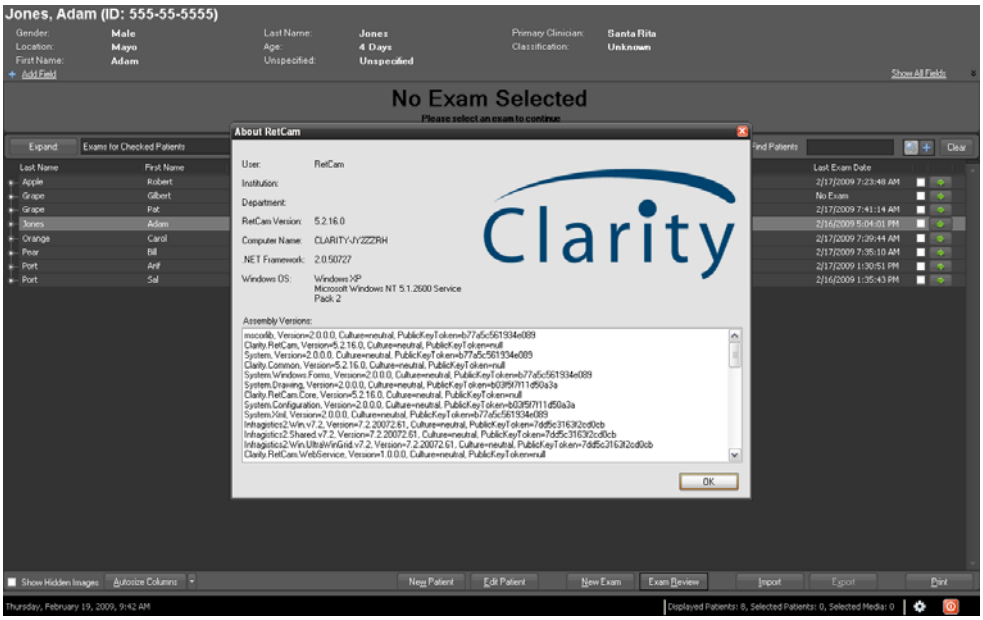

Figure 40 About Clarity software

Select **User Preferences**.

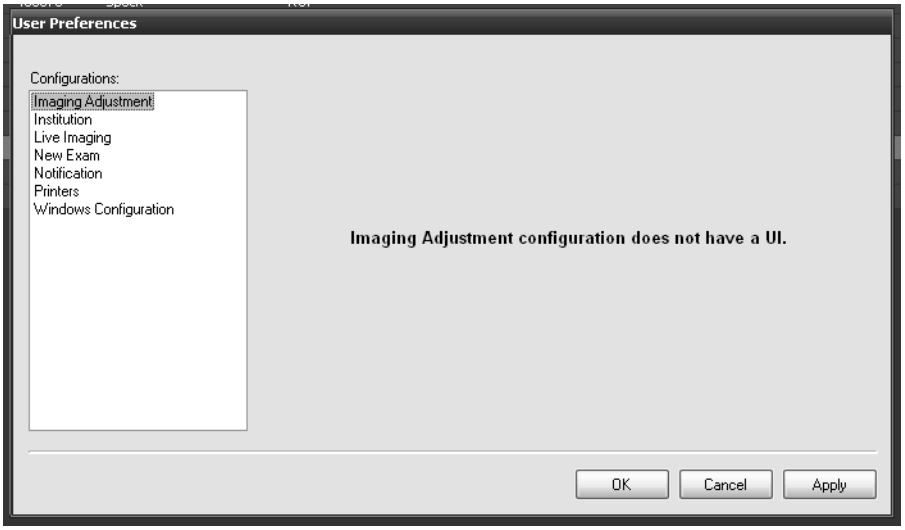

Figure 41 User Preferences screen

Select from the following options:

Imaging Adjustment	Not available
Institution	Add the name of the Institution, Department and Location.
Live Imaging	Not applicable
New Exam	Set the Pre-set Imaging Configurations for new exams.
Notification	Not applicable
Printers	Set the Default Image and Report Printer.
Windows Configuration	Set Date and Time, Display, Network Connections, Printers and Faxes, Region and Language, Security Center and Sound.

Institution

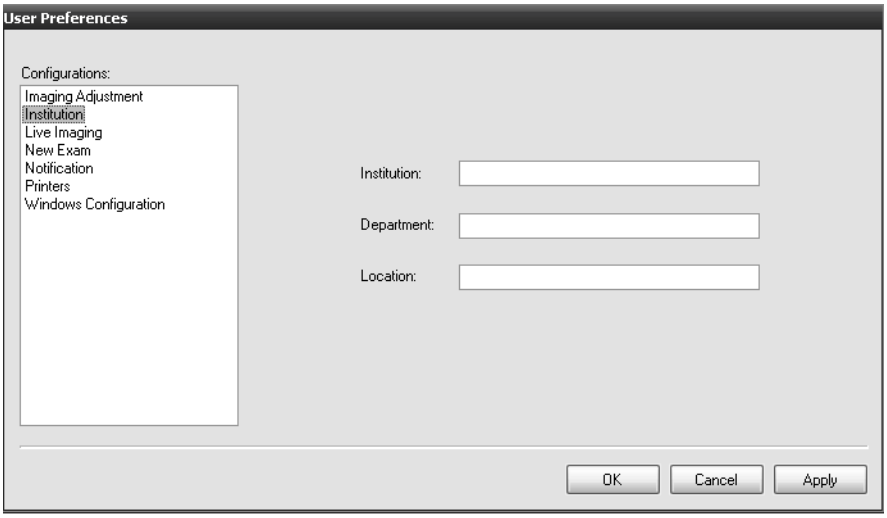

Figure 42 User Preferences: Institution

New Exam

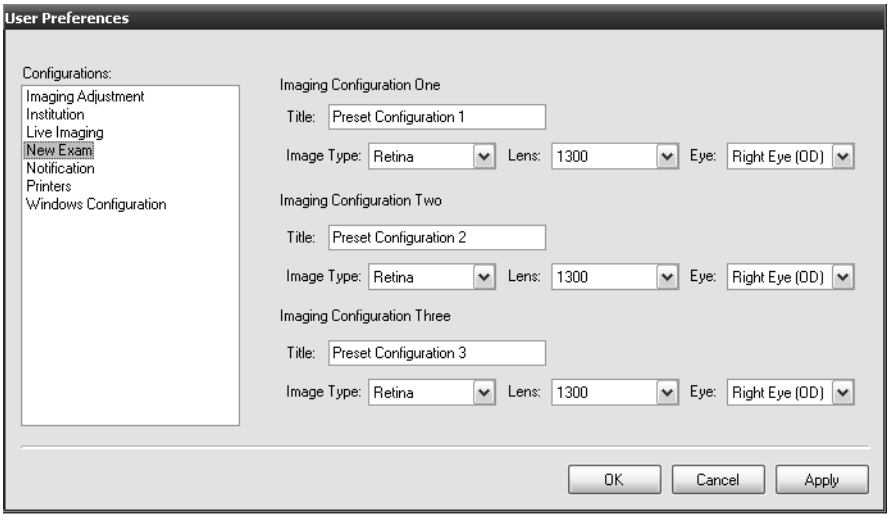

Figure 43 User Preferences: New Exam

Once the New Exam preset configurations are adjusted, select **Apply** to initiate the change or **Cancel**. Select **OK** to exit the screen.

Printers

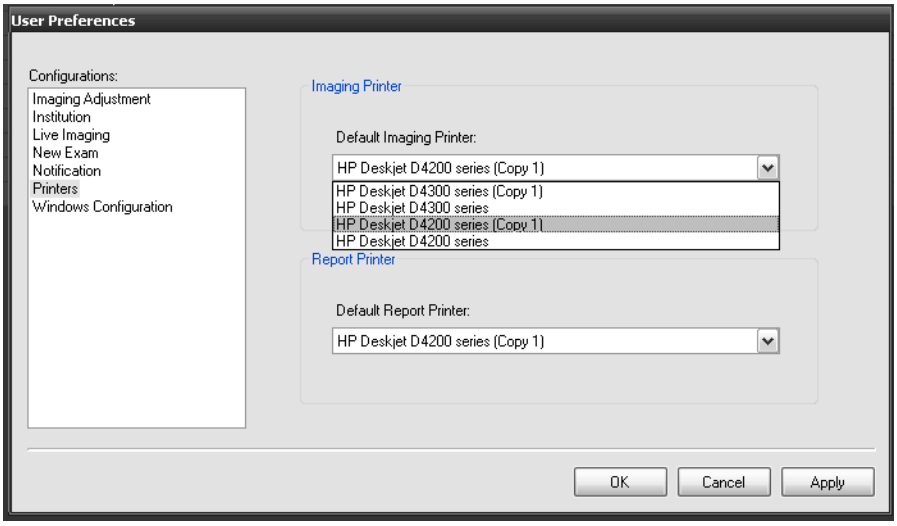

Figure 44 User Preferences: Printers

Select the default printers, then select **Apply** to initiate the change or **Cancel**. Select **OK** to exit the screen.

Windows Configuration

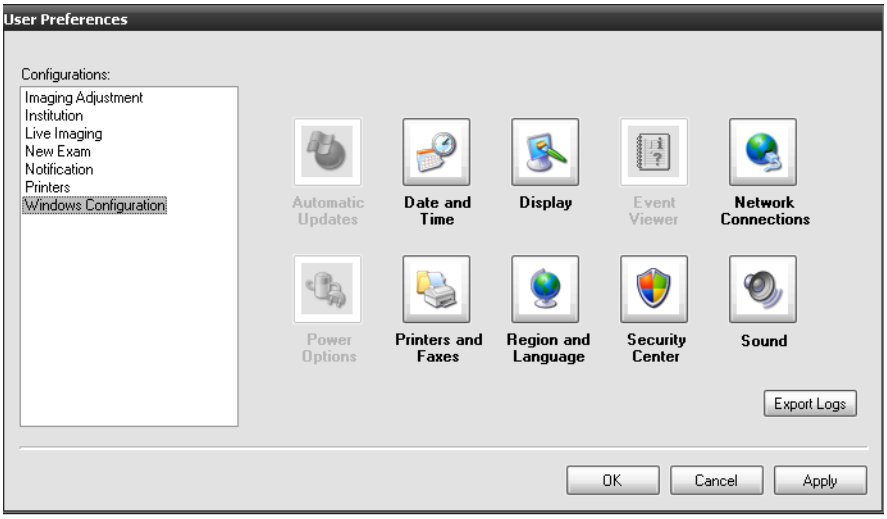

Figure 45 User Preferences: Windows Configuration

Select the desired Windows configuration icon and make changes where needed. Select **Apply** to initiate changes or **Cancel**. Select **OK** to exit the screen.

8 Maintenance and Support

This section addresses maintenance and support under the following topics:

Recommended Maintenance Schedule

Between patients: Clean and inspect lens piece.

Weekly: Wipe down the system.

Monthly: Inspect cables and connections for wear.

Burned out bulb: Replace illumination bulb

Blown fuse: Replace system fuses

Cleaning Procedures

Cleaning the Lens Piece

The patient contact area lens should be cleaned immediately after use to prevent the coupling gel from hardening.

1. Wipe away debris from the front lens piece surface with a soft dry tissue, sterile water soaked tissue, or combination.
2. Then, using a clean soft cloth (such as sterile gauze) saturated in a fresh solution of 70% IPA (Isopropyl alcohol), gently wipe the front of the lens piece, being sure to pay special attention to the concave contact lens area, to remove any remaining debris; at least eleven wipes with a clean saturated cloth. Pre-packaged swabs (such as ReliOn Alcohol swabs or BD Alcohol Swabs) may be used.
3. Rinse surface thoroughly using sterile water.
4. Air dry.
5. Verify that the lens surface is free of debris and coupling gel. Repeat above steps if necessary.
6. Inspect the lens for damage and clarity. Do not use the lens if there are chips, cracks, or rough edges on the lens which may injure the patient’s eye.

Caution: Do not Autoclave any part of the system.

Caution: Never immerse the entire lens piece or handpiece in any liquid solution. If necessary, only the distal 4 mm can be immersed. See Figure 46.

Warning: If you clean or disinfect, rinse the lens with sterile water to avoid corneal deepithelialization that may be caused by residual solution.

Note: For disinfection, see attached Information Statement from the American Academy of Ophthalmology.

Caution: As disinfection solutions may cause corrosion of the lens piece, soak times that exceed the recommendation should be avoided.

Note: Permissible immersion depth is illustrated in Figure 46 below. It is important not to immerse the joint where the polished metal tip meets the painted housing, since it is susceptible to corrosion.

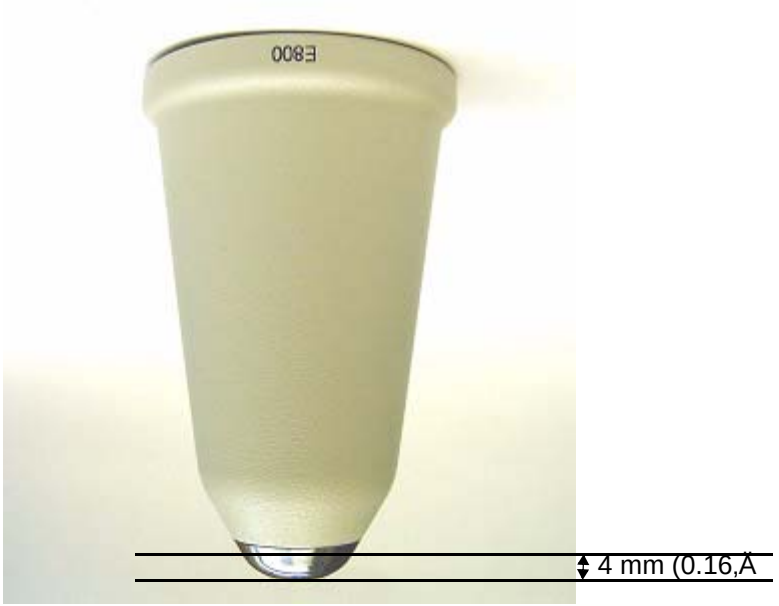

Figure 46 Inverted lens piece showing permissible depth of immersion

Cleaning the Rest of the System

As with any medical device, use good public health practices when handling the equipment, based on CDC guidelines. In addition, as with typical office equipment, a gentle wiping with a cloth moistened with mild soap and/or water is recommended. Do not spray cleaning solutions directly on the computer or other modules, spray the cloth instead. The cart and side panels also cannot be sprayed,

but only the cloth with which you wipe, to avoid introducing spray or mist inside the system. Use only a mild soap and/or water solution.

The lens piece should be checked before each use for damage to the front contact lens and surrounding surface. The interconnect cable and connectors should be checked for damage to the end connectors and protective covers.

WARNING: Always inspect the lens before use for damage such as chips, cracks or roughness that could injure the patient's eye.

Disposal of Materials

Dispose of waste materials according to local and national requirements. Contact Clarity Service if additional assistance is required.

Information Statement

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

Minimizing Transmission of Bloodborne Pathogens and Surface Infectious Agents in Ophthalmic Offices and Operating Rooms

Introduction

This document is intended to provide guidance to ophthalmologists and their staff about minimizing transmission of infection in their offices and operating rooms. This document addresses prevention of bloodborne pathogens such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and other viruses, such as adenovirus and herpes simplex virus. These recommendations are mainly based on broad guidelines issued by the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Labor for health care workers.

Bloodborne pathogens may be present in blood, blood-contaminated products or other bodily fluids especially if contaminated with or mixed with blood. Percutaneous injuries (e.g., a needlestick or cut with a sharp object) represent the greatest risk of transmission of bloodborne pathogens to health care workers. Universal precautions apply to blood and other body fluids containing visible blood, but not to tears unless they contain visible blood.[1] The use of universal precautions, including handwashing and barriers, reduces contact with blood and bodily fluids, thus reducing exposure of health care workers to bloodborne pathogens. The use of safety devices and techniques to reduce handling of sharp instruments also reduces the number of percutaneous injuries.

Exposure to HIV in health care settings has been of major concern. As of June, 2000, the Centers for Disease Control and Prevention (CDC) received reports of 56 U.S. health care personnel with HIV transmission associated with occupational exposure, and another 138 reports of possible transmission to date.[2] For health care personnel exposed through percutaneous means to HIV-infected blood, the estimated risk for HIV infection is 0.3%.[2] Risks associated with a mucous membrane exposure are estimated to be 0.09%.[2] Risks for HIV seroconversion after a percutaneous exposure have been found higher for those exposed to a larger quantity of blood, (i.e., a device visibly contaminated with blood, a needle being placed directly in a vein or artery, or a deep injury) or when the source patient was terminally ill with AIDS.[2]

Transmission of HBV poses a risk to health care workers. In 1994, approximately 1,000 health care workers were infected with HBV from occupational exposure.[2] Since implementation of routine preexposure vaccination of health care personnel and precautions to prevent exposure to blood, there has been a significant decrease in HBV infection among health care personnel.[2] HBV is transmitted by mucosal or percutaneous exposure to blood and serum-derived body fluids from persons with acute or chronic infection. The risk of developing clinical hepatitis from exposure to the blood that was both hepatitis B surface antigen (HbsAg) and hepatitis E antigen (HbeAg) positive was 22 to 31%.[2] Any person who is seropositive for hepatitis B surface antigen can be infectious. The CDC recommends that health care personnel who have routine contact with blood and bodily fluids be vaccinated.[3] For applicable settings, the OSHA standard requires that hepatitis B vaccine be made available to personnel with occupational exposure to blood, at the employer's expense.[4]

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HCV is the cause of most parenterally transmitted cases of non-A, non-B hepatitis in the U.S. There is no vaccine currently available and postexposure prophylaxis has not appeared effective in preventing infection. HCV is thought to be transmitted relatively rarely through occupational exposure to blood.[2] The incidence of seroconversion after percutaneous exposure to an HCV-positive source is estimated to be 1.8%.[2] Hepatitis C virus (HCV) has been isolated in tears and aqueous humor.

Adenovirus has been the main cause of nosocomial outbreaks of conjunctivitis. These outbreaks have mostly occurred in eye clinics or offices. Adenovirus can survive for long periods on environmental surfaces and ophthalmic instruments can become contaminated and transmit infection. Handwashing, glove use and disinfection of instruments can all help to prevent or limit the transmission of adenovirus. Infected personnel should not provide patient care for the duration of symptoms after onset of adenoviral conjunctivitis

Background

The National Society to Prevent Blindness, in cooperation with the American Academy of Ophthalmology assembled a Task Force to examine the risk of acquiring HIV infection in the course of eye examinations and treatments. The Task Force helped develop precautions to reduce spread of pathogens that might be present in tears.[5]

In August 1987, the Centers for Disease Control and Prevention (CDC) issued revised recommendations for the prevention of HIV transmission in a health-care setting.[6] This was followed two months later by a joint advisory notice from the U.S. Department of Labor and the U.S. Department of Health and Human Services regarding the protection against occupational exposure to HBV and HIV.[7] These documents addressed the risk that health care workers may face in the course of their duties and made broad recommendations labelled universal precautions that all health care workers should follow. Neither document distinguished the risks and needs of healthcare workers in ophthalmology from any other health care occupation.

In June 1988, the CDC further clarified their recommendations, particularly as they relate to the protection of health care workers, by stressing the far greater risk of bloodborne viral infections (e.g., HIV and HBV) posed by blood and blood-contaminated bodily fluids than by such bodily secretions as tears.[8] In that document, they noted that "Universal precautions do not apply to ... nasal secretions, sputum, sweat, tears... unless they contain visible blood." Thus, normal tear exposure does not require bloodborne pathogen precautions. In June, 2001, the U.S. Public Health Services updated recommendations for the management of occupational exposures to HBV, HCV and HIV.[3]

In March 1992, the Occupational Safety and Health Administration (OSHA), issued a set of regulations entitled, "Occupational Exposure to Bloodborne Pathogens, "which requires that employers establish safeguards which protect workers against hazards related to bloodborne pathogens.[4] These regulations require identification of who is at risk of occupational exposure, the communication of hazards to employees at risk for exposure, exposure prevention control measures, and what to do if an exposure occurs. In April 2001, the Needlestick Safety and Prevention Act became effective, revising the bloodborne pathogens standard to require employers identify and make use of safer medical devices which can be used to reduce worker exposure.[9]

In 1992, the American Academy of Ophthalmology Public Health Committee developed updated recommendations for ophthalmic practice in relation to HIV.[10] The Committee noted that there were two distinct areas of concern to ophthalmic medical personnel and patients:

1. Transmission of ocular surface infectious agents such as adenovirus or herpes virus. Prevention of transmission of these pathogens requires good hygienic techniques, such as routine hand washing, tonometry cleaning and trial contact lens disinfection.

2. Transmission of bloodborne pathogens such as HIV or HBV. Prevention of transmission of these agents requires the use of bloodborne pathogen precautions, which include the proper use of gloves, needle disposal and other precautions such as administering hepatitis B vaccine in workers exposed to bloodborne pathogens.

Recommendations

The Committee recommended specific measures that would provide adequate protection for the patient, for health care workers in the ophthalmic care setting, and for the ophthalmologist. This document updates four areas:

- Procedures for protection of the patient
- Procedures for protection of the staff
- Procedures for protection of the ophthalmologist
- Responsibilities toward patients with known or suspected HIV infection

I. Procedures for Protection of the Patient

Protection of patients from exposure to the HIV during examination and treatment of eye disorders incorporates

the application of good public health principles and specialized precautions. Since the infection was first recognized in 1981, there has been no evidence to indicate that the HIV has been transmitted through any of the diagnostic or surgical procedures performed by ophthalmologists. According to the CDC, the likelihood of transmission through contact with tears is extremely remote.[8] However, because the virus is potentially lethal, is present in surface epithelia in the eye and in low titers in tears and ocular fluids of infected individuals, and can (in theory at least) be transmitted through mucous membranes, public health officials have recommended that reasonable precautions be taken. Furthermore, because many HIV carriers may be unaware of their infection and show no sign of the disease, the following recommendations should be routinely used for **all** patients. Recommendations for the safe usage of ophthalmic instruments and contact lenses are provided. These guidelines represent good, general ophthalmic technique, because they reduce the risk of transmitting both bloodborne pathogens (HIV, HBV and HCV) and surface infectious agents (e.g., herpes simplex virus, adenovirus, etc.) likely to be encountered in patients presenting for eye examinations.

Recommendations

A. Handwashing.

Handwashing represents the single most effective means of avoiding the risk of transmitting or acquiring infections in the course of examination.[11] The CDC recommends that ophthalmic medical personnel performing eye examinations or other procedures involving contact with tears should wash their hands immediately after a procedure and between patients.[5] Handwashing should be encouraged when there is any doubt about the necessity for doing so. For routine handwashing, a vigorous rubbing together of all surfaces of the lathered hands is recommended for at least 10 seconds, followed by a thorough rinsing under a stream of water.[11] Plain soap can be used for handwashing for most routine activities. Gloves may be used as an extra margin of safety. When gloves are worn, handwashing is still recommended because gloves can become perforated and bacteria can grow rapidly on gloved hands. If there are cuts, scratches, or dermatological lesions (e.g., weeping lesions) on the hands, then use of gloves is advisable.

B. Eyedrops.

The bottle tip should not come into direct contact with the patient's tears or conjunctiva. If the tip does touch the patient, the bottle should be discarded.

C. Gowns, masks and protective eye wear.

Gowns, masks and protective eyewear are unnecessary for the usual ophthalmic examination.

D. Disinfection procedures.

Disinfection is a process to eliminate most or all pathogenic microorganisms from inanimate objects, such as medical devices or equipment.[12] This is usually performed using chemicals known as germicides or disinfectants. High-level disinfection kills all organisms and is performed suing a germicide which is regulated by the Food and Drug Administration. The CDC recommends that if there are questions about high-level disinfectants or how to disinfect a particular medical device, the office should contact the manufacturer of the product.[13]

The CDC has recommended the following, which are proven to inactivate infectious HIV, herpes simplex virus, and adenovirus.[5]

- Wiping clean and then disinfecting with bleach is recommended by the CDC as an effective way to inactivate HIV. Remove the entire prism from the tonometer and place it in a suitable receptacle that allows the applanating surface and adjacent 2–3 mm of the tonometer to be immersed in a 1:10 dilution of household bleach (sodium hypochlorite). One method uses a Petri dish with small holes drilled in the lid, which allows just the tonometer tip to be partially immersed in the solution.[14] After a five-minute period of soaking, the tip should be washed under running water and dried before use. Two tonometer prisms should be available so that one can be used while the other is being disinfected. Soaking the entire tip may eventually remove the coloring of the etched calibration marks. These disinfecting solutions should be changed at least once daily.

- As an alternative, the CDC recommends that a similar approach with a 5 to 10 minute exposure to a fresh solution of either 3% hydrogen peroxide, 70% ethanol, or 70% isopropanol can be followed. These solutions need to be changed at least twice daily.

Goldmann-type Tonometers

A recent study compared several methods of disinfecting Goldmann tonometer tips, which were inoculated with hepatitis C virus.[15] The methods that resulted in the greatest decrease in concentration of HCV RNA were a 5-minute soak in 3% hydrogen peroxide or 70% isopropyl

alcohol following by washing in cold water. A 5-second 70% isopropyl alcohol wipe was not as effective, and a 5-second wipe with povidone iodine was more effective than the isopropyl alcohol wipe in reducing HCV RNA.

The washes are important to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Schiotz Tonometer

The tonometer should be dissembled between each use, cleaning the barrel with two pipe cleaners (the first soaked in alcohol, the second dry) and the footplate with an alcohol swab. All surfaces must be dried before reassembly. Disposable covers are also available.

Non-contact Tonometers

The non-contact tonometer may not make contact with the cornea or tears, but may cause micro-aerosol formation. The front surface may be wiped with an alcohol-soaked sponge since it may occasionally touch the eye.

Digital Pneumotonometer

Tips of pneumotonometers should be cleaned with an alcohol sponge, taking care that the surface is dry before using it again. It is important to allow the alcohol to evaporate completely to avoid damage to the corneal epithelium.

Diagnostic Contact Lenses (Goldmann, etc.)

The lens is inverted so that the contact lens surface is uppermost. The outer casing and inner surface of the lens are then vigorously wiped with an alcohol sponge
As an alternative, the inner cup may be filled to the rim or partly immersed within a fresh 1:10 dilution of household bleach. After five minutes, the bleach is removed and the device is briskly irrigated with running water and dried. This method allows cleansing of the outer surface of the lens as well as the contact portion without exposing the anti-reflective coating on the operator surface of the contact lens to the bleach. It is important to rinse to avoid corneal de-epithelialization that might be caused by residual disinfectant solution.

Other Instruments That May Come Into Contact With Patients

The HIV is a fragile virus and there is no evidence of casual spread from surfaces of ophthalmic instruments. However, it is known that other viruses, such as adenovirus, may persist for many hours on a dry surface and, thus, could conceivably be transmitted to other patients.[16] Therefore, if an instrument, such as a slit lamp biomicroscope, has been used for a patient who is suspected of having an ocular infectious disease, it is strongly recommended that the surfaces on the instrument be cleaned with alcohol or bleach.

Trial Fitting Contact Lenses

Contact lenses need to be disinfected between patients. Rigid gas permeable and hard contact lenses can be disinfected using a hydrogen peroxide or a chlorhexidene-containing disinfectant system. Soft contact lenses can be disinfected with either hydrogen peroxide or a heat disinfection system.[5]

E. Tissue Transplantation.

The Eye Bank Association of America has strict criteria in place to screen corneal and scleral tissue for transplantation, to prevent transmission of diseases. There have been no confirmed cases of occupational transmission of transmissible spongiform encephalopathies, such as Creutzfeld-Jakob disease. The CDC recommends use of stringent chemical and autoclave sterilization methods for heat-resistant instruments that come into contact with high infectivity tissues in patients with suspected or confirmed CJD.[17] For infection control of transmissible spongiform encephalopathies, the World Health Organization recommends the following in situations where there is contact with high infectivity tissues in patients with suspected or confirmed CJD:[18]

1. Use single-use surgical instruments
2. Avoid mixing instruments used on tissues of high infectivity vs. no infectivity
3. Destroy re-usable instruments, where possible
4. If destruction is not possible, decontaminate instruments.

The Risk of Acquiring HIV Infection from Ophthalmic Medical Personnel

The risk of patients being infected by an ophthalmologist or ophthalmic medical personnel who has been infected with the HIV is considered extremely remote. Standard office practices, as discussed above, will minimize even the unlikely risk of contamination of patients. Surgical patients are protected by the routine use of barriers (e.g., gloves). Certainly, an instrument that punctures the skin of an ophthalmologist or the surgical assistant must be removed from the operating field and sterilized. The surgeon or assistant must reglove after all bleeding has stopped and any residual blood has been removed.

The CDC Guideline for Infection Control in Healthcare Personnel also provides advice about management of patient contact and other situations when health care personnel have HIV and other illnesses which could be transmitted to patients.[19]

II. Procedures for Protection for the Staff

Protection of the ophthalmic medical personnel involves preventive measures to avoid infection with ocular surface contaminants (such as adenovirus or herpes simplex virus), as well as bloodborne pathogens (such as HIV, HBV and HCV).

Bloodborne pathogen precautions further reduce the unlikely risk of contamination of the ophthalmic medical personnel and patient, alike. Employers under OSHA's rule with health care workers who are exposed to bloodborne pathogens are required to establish a program that informs employees and employers of the risks of occupational exposure to bloodborne pathogens and how to reduce those risks.[3]

Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA's bloodborne pathogen precautions; but exposure to human tears does require good office hygiene practices such as handwashing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions.

As the prevalence of HIV infection continues to increase throughout the United States, it is inevitable that patients carrying HIV will be more commonly encountered in eye examining rooms and in surgery. Some of these patients will be known to be infected with the HIV, but in many, it will be unrecognized. All health care personnel engaged in delivering ophthalmic care to such patients might, in the course of their normal duties, be exposed to the blood of individuals who may be shedding the virus. Although the risk of infection in these circumstances appears to be extremely remote, precautions by health care employers and employees are justified as recommended by the OSHA and the CDC.

The following recommendations for hygienic procedures to be used in the delivery of eye care to patients are effective ways to minimize this risk as well as the risks of contracting or transmitting other much more common infectious diseases encountered in patients. Because it is impractical to identify all patients who may be carrying these infectious agents, these recommendations should be the routine for all patient encounters.

General Precautions Against Infection – Office

A. Handwashing.

The hands should be washed with soap and water and thoroughly dried on a fresh or disposable towel between each eye examination. Fingernails should be kept short and clean. The hands and fingers should be inspected frequently for cuts, abrasions, and breaks in the skin or paronychia.

B. Gloves.

The CDC suggests in its recommendations for the prevention of HIV transmission in health care setting, released in 1987[7], and updated in 1988[8], that:

> "All health care workers should routinely use appropriate barrier precautions to prevent skin and mucous membrane exposure when contact with the blood or blood-contaminated fluids of any patient is anticipated. Gloves should be worn for touching blood and blood-contaminated fluids, for handling items or surfaces soiled with such fluids and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other bodily fluids. Hands should be washed immediately after gloves are removed.
>
> Health care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
>
> Pregnant health care workers are not known to be a greater risk of contracting HIV infection than health care workers who are not pregnant; however, if a health care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission."

In accordance with these recommendations, disposable gloves should be readily available for all ophthalmic medical personnel and they should be instructed regarding the rationale for wearing gloves and their appropriate usage. It should be noted particularly that gloves:

- Are not a substitute for handwashing, and
- Are for single use only, and should be discarded after each patient encounter.

C. Gowns and Masks.

Gowns and masks are unnecessary in the normal ophthalmic office setting.

D. Protective eye wear.

In situations when splashing with blood or blood-contaminated fluids may be anticipated, protective eyewear is indicated.

E. Handling of tissue.

In the course of assisting in the examination of eye patients, ophthalmic medical personnel may be required to handle the eyelids and surrounding facial skin and thus, may come in contact with tears and the conjunctival membrane. To minimize direct contact with these tissues, particularly if the patient has a known or suspected eye infection, ophthalmic medical personnel should be instructed in the use of gloves or in "no-touch" techniques involving the use of cotton-tipped applicators to stabilize the tissues whenever possible.

F. Hepatitis B vaccination.

Ophthalmic medical personnel who frequently come in contact with needles, blood or blood products are advised to receive hepatitis B vaccine to avoid infection with the virus.[3] OSHA regulations require that the employer make hepatitis B vaccine available to all employees who have occupational exposure.[4]

Procedures

A. Handling of sharp instruments.

The CDC has recommended that all health care workers adopt precautions to prevent injuries caused by needles, scalpels and other sharp instruments or devices[8]:

- During procedures
- When cleaning used instruments
- When disposing of used needles, and
- When handling sharp instruments after procedures

To prevent needlestick injuries, ophthalmic medical personnel should be instructed in the proper handling of needles, i.e., needles should not be recapped, or purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. Health care workers should be instructed to place disposable syringes and needles, scalpel blades and other sharp items in puncture resistant containers following their use. Puncture resistant containers should be provided and should be located as close as practical to the area where needles and syringes are in use. Newer devices have engineering controls such as injury protections and needleless systems to minimize injuries.

OSHA's revised Occupational Exposure to Bloodborne Pathogens Standard now requires that the employers governed by this rule review annually and update to reflect changes in technology that could reduce exposure to bloodborne pathogens, and maintain a sharps injury log.[20] OSHA's Bloodborne Pathogens Standards applies to all employers with employees who have occupational exposure to blood or other potentially infectious materials. However, workplaces with 10 or fewer employers are exempt from OSHA recordkeeping requirements, including a Sharps Injury Log.[21]

B. Fluorescein and Indocyanine green (ICG) angiography.

It is recommended that photographers and other health care workers who may come in contact with blood while performing fluorescein and ICG angiography wear gloves and adhere to the procedures as outlined in this section.

C. Contact lens fitting.

Ophthalmic medical personnel involved in the fitting of contact lenses should be instructed in the precautions outlined by the CDC for disinfection of lenses.[4]

D. Minor office surgical and diagnostic procedures.

During the performance of minor surgical and diagnostic procedures, particularly where contact with blood or blood-contaminated fluids may occur, gowns, disposable gloves and masks, and protective eyewear should be worn.

Surgery

Ophthalmic medical personnel assisting at eye surgery should be instructed to avoid the direct handling of needles and those parts of instruments that have come into contact with body tissues and fluids. Thus, needles should be manipulated with forceps or needle holders rather than by the gloved fingers, instruments should be held by the handle rather than by the tips, and the cleaning of instruments should be performed in such a way that accidental perforation of the gloves is avoided. If an instrument punctures a glove or the skin, it must be removed from the operating field and sterilized. These practices should be incorporated into standard operating room infection control procedures and should be monitored for compliance, as are other infection control procedures.

If an ophthalmic medical personnel does accidentally sustain a skin puncture, the following actions should be taken. The individual should temporarily discontinue participation in surgery (if possible) and cleanse the wound for five minutes with an antiseptic solution.

The wound should then be dressed with a bandage after rescrubbing. If there is no oozing or weeping of the wound, the person may reglove, and complete the surgery.

Under experimental conditions, it has been reported that oral polio vaccine virus was cultured from the laser plume after excimer laser ablation.[22] Another experimental study postulated that infectious virus particles could be aerosolized during excimer laser photoablation.[23] Another study using a model system did not find any transmission of virus by the excimer laser plume.[24] It seems prudcnt then to maintain the same procedures in excimer laser surgery procedures as practiced as in other surgical procedures, e.g., masks, gloves, sterilization of instruments, etc.

Management of Exposures

These recommendations are based on the U.S. Public Health Service Guidelines, published in 2001.[2] Occupational exposures are considered urgent medical concerns so that timely management can be administered.[2] Studies show that postexposure prophylaxis should be initiated as soon as possible, because it is most effective within 24 to 36 hours after exposure. However, even after 24 to 36 hours, it can be considered, because it might still be effective.

If a person has been exposed to a source person already known to be seropositive for HIV or there is a strong likelihood that the source person is HIV infected, then postexposure prophylaxis (PEP) can be initiated as soon as possible, in consultation with physicians with expertise in antiretroviral therapy and HIV transmission. If the source person's HIV status is not known, the use of PEP can be decided on a case-by-case basis. All persons with occupational exposure to HIV should receive follow-up counseling, testing and medical evaluation. For HIV PEP, recommendations include a basic 4-week regimen of drugs, if tolerated, and an expanded regimen for exposures that pose an increased risk for transmission.[2,25]

If the source person is seronegative for HIV, then baseline testing or further follow-up of the exposed health care personnel is not necessary. Otherwise, health care personnel should be tested for HIV within hours of exposure. Serologic testing should be made available to all health care personnel who are concerned that they might have been infected.

For personnel exposed to HBV, it is recommended to initiate the hepatitis B vaccine series to an unvaccinated person, and provide PEP with hepatitis B immune globulin or hepatitis B vaccine in appropriate cases, preferably within 24 hours.[1]

For personnel exposed to HCV, the Public Health Service does not recommend immune globulin or antiviral agents as PEP.[2] However, there have been studies outside the United States that have utilized interferon early in the course of acute hepatitis C to prevent the establishment of chronic hepatitis C.[2,26] In case of percutaneous or mucosal exposure to blood, the CDC recommends that health care institutions have policies to follow-up for HCV infection, which could include testing of the source person for anti-HCV antibodies, and follow-up testing for anti-HCV antibodies of the affected personnel, if the source person is found positive for HCV.[2]

If there is exposure to blood, fluid containing visible blood, or other potentially infectious fluid (not including tears), then the status of the source person should be evaluated for HIV, HBV, and HCV infection as soon as possible.

It is recommended that health care organizations have systems in place for prompt reporting, evaluation, counseling, treatment and follow-up of occupational exposures to bloodborne pathogens.[2] Health care personnel should be educated to report occupational exposures immediately after they occur, because treatment can be most effective if administered as soon as possible after the exposure. Employers subject to OSHA regulations are required to establish exposure control plans that include post-exposure follow-up and to comply with incident reporting requirements.[4]

III. Procedures for protection of the ophthalmologist

Ophthalmologists might be at risk of acquiring HIV, HBV or HCV infection in their professional activities from two major sources: 1) the patient examination, and 2) the setting of surgical intervention.

General Precautions Against Infection – Office

The ophthalmologist personally should follow the same procedures designed to protect office staff and described in Section II. These include handwashing, wearing of gloves where appropriate and taking precautions to prevent injuries caused by needles, scalpels and other sharp instruments. Avoid touching one's own eyelids or contact lenses with the fingers without thorough hand washing.

In the normal ophthalmic office setting, gowns, masks and protective eyewear are usually unnecessary except in situations when splashing with blood or blood-contaminated fluids may be anticipated.

Minor Office Surgical and Diagnostic Procedures

The universal precautions should be observed when performing minor procedures and intravenous fluorescein angiography. In addition to gloves and masks, protective

eyewear should be used if there is a possibility of blood or body fluid splashing.

Surgery

Ophthalmologists are probably most at risk of exposure to HIV and other bloodborne pathogens while performing or assisting in surgery. The following procedures are recommended during surgical procedures:

- Adopt universal precautions for all patients
- Wear gloves when performing all injections
- Handle suture needles with needle holders only
- Develop techniques for safe handling and transfer of sharp instruments
- Follow guidelines given in Section II regarding surgery

IV. Responsibilities Towards Patients with Known or Suspected HIV Infection

Like all physicians, ophthalmologists have a moral and ethical responsibility for providing care to all patients, regardless of whether they are known to be infected with HIV, are known to be seropositive or fall within a "high-risk" group.

Ophthalmologists and ophthalmic medical personnel are at little risk of contracting HIV infection in the course of routine clinical practice. Risks may be further minimized when dealing with those known to be seropositive or suffering from clinical AIDS, but one should remain cognizant of the fact that many seropositive individuals have not been tested. Given the above scenario, bloodborne precautions are warranted for all appropriate patients.

Conclusion

The risk of contracting HIV infection in the ophthalmic healthcare setting is estimated to be extremely remote. Although HIV has been isolated from tears and other ocular fluids, the titer is extremely low and is considered by many authorities to be below an inoculating dose. To date, there is no evidence that the infection has been acquired from contact with tears. However, it must be remembered that these precautions will be effective against other more infectious agents than may be encountered in patients with HIV infection. These OSHA and CDC guidelines are intended to help protect the public and ophthalmic medical personnel, and minimize transmission of bloodborne pathogens and surface infectious agents.

Additional Resources:

Further information on the CDC guidelines can be obtained by viewing the CDC website for Division of Healthcare Promotion http://www.cdc.gov/ncidod/hip/.

Further details on the OSHA regulations including regulations governing HIV and HBV research laboratories and production facilities can be obtained by viewing the OSHA website (http://www.osha.gov/) or ordering publications online (http://www.osha-slc.gov/OshDoc/Additional.html)

Occupational Safety and Health Bloodborne Infectious Disease
www.cdc.gov/niosh/bbppg.html

State needle safety legistation: www.cdc.gov/niosh/ndl-law.html

Exposure management resources:

National Clinicians' Postexposure Prophylaxis Hotline (PEPline)
1-888-448-4911

Needlestick! www.needlestick.mednet.ucla.edu

Hepatitis hotline 1-888-443-7232

Reporting to CDC: Occupationally acquired HIV infections and failures of PEP
1-800-893-0485

HIV/AIDS treatment information service
www.hivatis.org

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Fuse Replacement

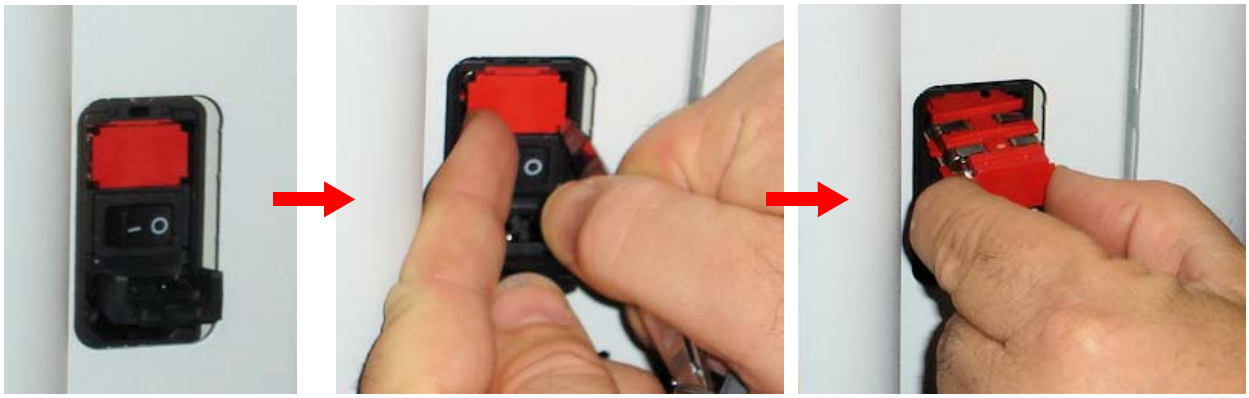
Locate the power entry module on the lower right side of the rear of the cart. Make sure to remove the power cord before proceeding any further. (See Figure 47.)

Figure 47 Power Entry Module

Using a flat blade screwdriver, gently pry open the cover of the fuse holder at the top of the power entry module. (See Figure 48.)

Figure 48 Opening the fuse holder cover

Remove the fuse holder. (See Figure 49.)



Cover open | Gently pry at edges to start removal | Finish removal with fingers

Figure 49 Removing the fuse holder

Remove the blown fuse from the fuse holder and replace it with a new fuse of same type and rating. (See Figure 50.) Reinsert the fuse holder.

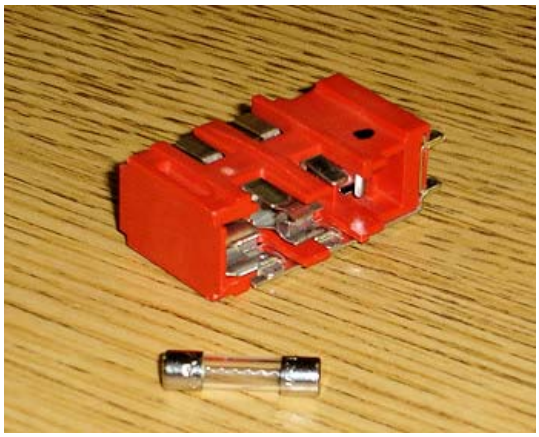


Figure 50 Blown fuse removed

CAUTION: For continued protection against risk of fire, replace only with same type and rating fuse.

Replacement fuses are available from Clarity Customer Service.

Replace Illumination Lamp/Bulb

WARNING: Appropriately shutdown and unplug the unit to allow the bulb to cool before replacing it.

Note: Replacement bulbs are available from Clarity Service.

1. If not already OFF, turn OFF the Main Power (see page 20).
2. Disconnect the power cord from the wall.
3. Unplug the fiber optic cable from the front panel.

4. Remove the two screws from the lamp assembly drawer.

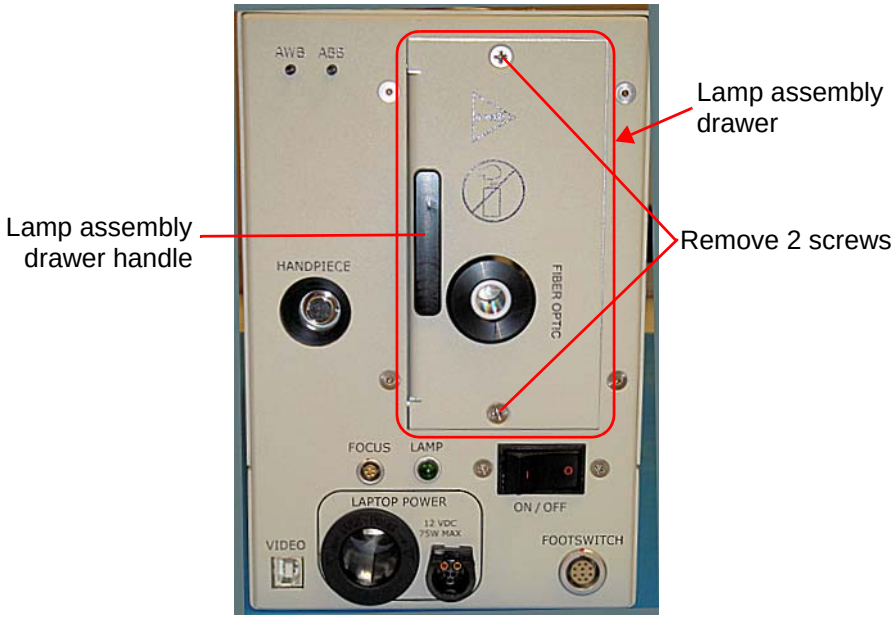


Figure 51 Front panel showing the lamp assembly drawer

5. Grip the handle on the lamp assembly drawer. Pull the drawer out slowly. Stop when the bulb is fully exposed.

Figure 52 Open lamp assembly drawer

6. Push the lamp ejector as shown.

Figure 53 Eject the bulb

7. Carefully slide the bulb out of the socket slots.
8. Catch the bulb.

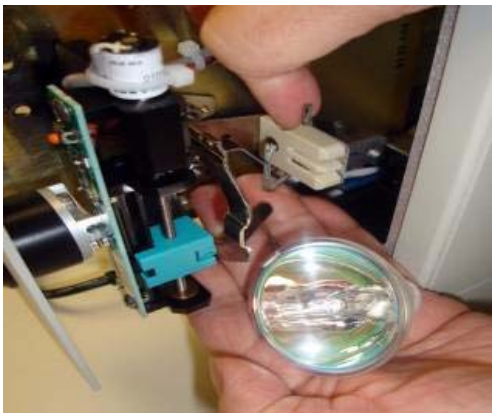


Figure 54 Catch the bulb

9. **Holding the new lamp only on the outside,** align the two pins of the bulb with the two slots in the socket. Push it all the way in.

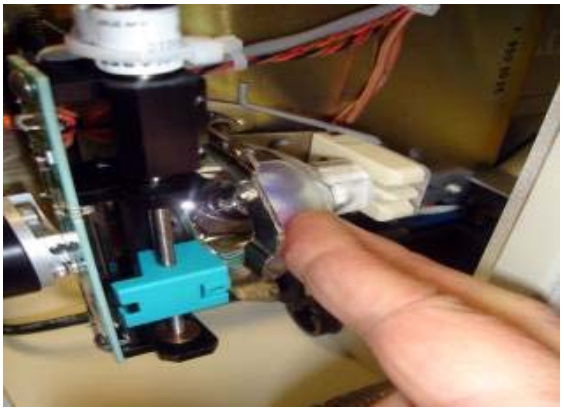


Figure 55 Insert new bulb

10. Carefully push the lamp assembly drawer back. Use caution to avoid pinching wires in the area.
11. Replace the two screws on the lamp assembly drawer and replace the fiber optic cable.

Figure 56 Replace lamp assembly drawer and fiber optic cable

Key Validation

Note: New RetCam Shuttle systems ship with their license key already registered and validated. However, significant changes to the system hardware or a re-load of the system software for any reason (including software upgrade) may require you to perform the key validation process as described below. Key validation requires that you get a license key from Clarity to use the revamped system, and you cannot request this key until after installation is complete. Since it may take up to two (2) business days to obtain a license key after submitting a request, we recommend that you affect system or software upgrades when you can manage two business days without use of the system.

Note: To ensure the preservation of your patient data and images, we strongly recommend that you perform a complete backup of the system's images before you begin any software installation.

When key validation is necessary, the Key Validation dialog appears when you start the system (and each time thereafter until you complete this step).

Figure 57 Key Validation dialog

Follow the instructions on screen: Call Clarity and provide to the customer support representative the large license number in the dialog (71339298 in the example above), which is unique for your system. You will be provided in turn a unique authorization key.

> Tip: You may also send the license number via email to **service@retcam.com** and receive the authorization key by return email.

You must enter the authorization key in the field and select **Validate Key** to access the system software. If you call, to make sure you enter the number correctly, we recommend you do not hang up until the number is accepted.

Technical Support

Technical Support Contact Information

Customers outside the US, please contact your distributor for technical support.

In the US, you have the following options:

Telephone

Toll-free: (800) 215-6005

Fax: (925) 251-0078

Telephone support is typically available between the hours of 9am and 5pm Pacific Time.

Send correspondence to:

Clarity Medical Systems, Inc.

5775 West Las Positas Blvd.

Pleasanton, CA 94588

USA

E-mail

service@retcam.com

Our US technical support staff will respond to your questions as soon as a staff member is available. In most cases, you should receive an answer within 48 hours. Complex questions that require testing or special research may take longer.

Note: Questions about products no longer under warranty and questions other than to explain ordinary use of the product may incur service charges. Please ask for an hourly quotation before incurring charges.

9 Service

CAUTION: This section is intended for use by qualified technical personnel only. If in doubt, please contact the Clarity Service before proceeding.

Spare parts and supplies can be ordered by calling or faxing the part description and part number to Customer Service.

Consumables

Part Description	Part Number
Illumination Bulb (halogen)	02-04-501
Fuses 3-amp 250 VAC 5x20mm (slo-blo)	20-000097
USB stick	03-12-025
User Manual (Software v. 4.x)	20-000106
User Manual (Software v. 5.x)	20-000225

Components

Part Description	Part Number
Notebook Computer - Durabook	20-000067
Notebook Computer - Hewlett Packard	20-000216
Footswitch	20-000009
Handpiece (metal shell)	01-00-201
Handpiece (plastic shell)	21-100064
EO box	20-000008
Portrait Lens (PL100) for use with the metal shell handpiece	PL100
Portrait Lens (PL200) for use with the plastic shell handpiece	PL200
Standard Baby Lens	B1200
Premature Infant Lens	D1300
High Contrast Lens	E800
High Magnification lens	C300

Servicing the Cart

The notebook computer, EO Box, Handpiece and Footswitch are modules that can be removed from the cart for replacement under the direction of the technical service department. Make note of the cable connections before removing a module.

Contact Clarity Technical Service for specific procedures and help troubleshooting problems to the module level before attempting repairs.

Notebook Computer Information

Note: The battery is not fully charged. Allow your battery to fully charge before using it (i.e., before disconnecting AC power). Calibrating the battery before use is also highly recommended. For information on the rechargeable battery of the notebook computer, please follow the laptop manufacturer's recommendations:

For the Durabook: http://usa.twinhead.com/PRO/N15RI

For the HPhttp://hp.com

Troubleshooting Guide

Problem	Troubleshooting Steps
No power to notebook computer	Check connections: Is the power cord plugged into the back of the system? • If not plug the power cord in. Is the main power switch in the back turned on? • If not then turn the main power on. Is the notebook power cable plugged into the notebook and the EO Box? • If not, plug cable in.
No light from handpiece	Verify the fiber optic cable from the handpiece is inserted in the fiber optic port of the EO box. Verify the power switch in the back of the system and on the front of the EO box are turned on. Turn the power switch OFF for 10 minutes and then turn it ON. This will allow the lamp to cool. If after these measures are taken the lamp does not turn on, then replace the illumination bulb. (See Replace Illumination Lamp/Bulb on page 71.)
No live image	Check connections: Is the USB cable from EO box to the notebook connected? Verify the cables are properly plugged in. Is the camera cable securely connected to the EO box? Verify the camera cable is inserted and threaded on.

Problem	Troubleshooting Steps
Unable to SNAP image from footswitch	Is the USB cable from EO box to the notebook connected? Verify the cables are properly plugged in. Close the RetCam Shuttle program and reboot the notebook.
Images do not transfer	Verify the Export path and subfolder match the intended destination.
No network connection	Contact your Information Technology (IT) department.

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10 Technical Specifications

Hardware

Physical

- 19” (483 mm) wide x 19”(483 mm) deep x 34”(864 mm) high
- Approximately 65 lbs. (30 Kg)

Electrical

- Power consumption: 250 VA maximum
- Input Power: 100-240V~, 50/60 Hz
- Fuse: T 3A/250V

Software

- MS Windows® XP SP2 operating system

Environmental Conditions

The system as delivered is intended for use indoors, at normal room temperatures, upright, on a level surface, with the brakes applied to the front casters.

Condition	Operating	Storage and Transport
Temperature	59º to 95º F (15º to 35º C)	-4º to 122º F (-20º to 50º C)
Relative Humidity	10% to 95% non-condensing	10% to 85% non-condensing
Atmospheric Pressure	20.7 to 31.3 inches Hg (70 to 106 kPa)	14.7 to 31.3 inches Hg (50 to 106 kPa)
Altitude	-1255 to 9882 feet (-382 to 3012 meters)	-1255 to 18288 feet (-382 to 5574 meters)

Notebook Computer

- Intel® Pentium® M 2.1 GHz processor
- 2GB Random Access Memory
- 80 GB hard drive
- DVD/R/RW drive
- 3 USB connections
- Audio
- 10/100 Ethernet Adapter
- Intel 128MB Video Adapter

Note: Specifications subject to change without notice.

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11 License Agreements

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